U.S. FOOD & DRUG ADMINISTRATION

COSMETICS *DIRECT*

Electronic Submissions Portal

Screenshots for Commenting
September 2023

https://www.fda.gov/cosmetics/registration-listing-cosmetic-product-facilities-and-products

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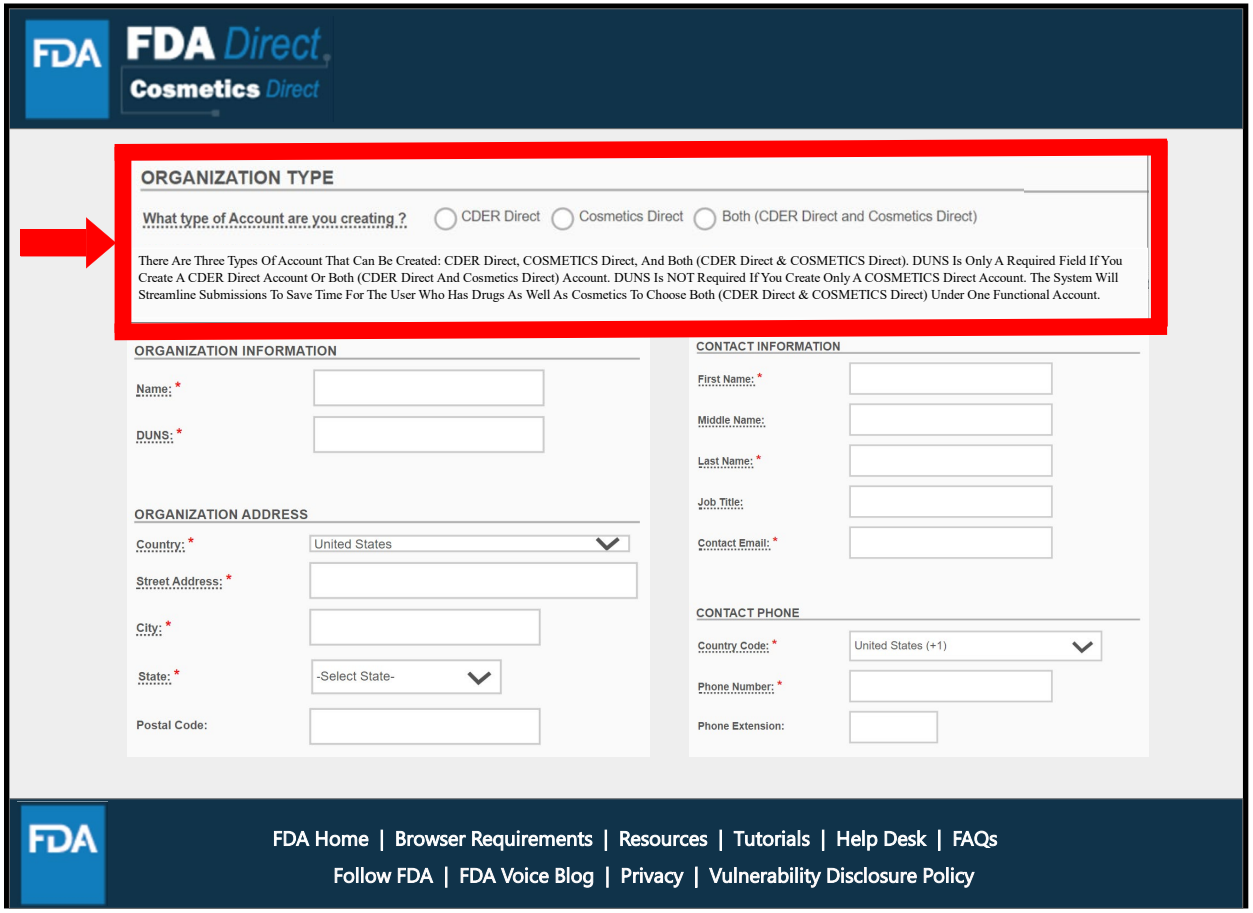
FDA DIRECT Home Page

The WELCOME TO FDA DIRECT provides short background info about each (CDER Direct and COSMETICS Direct). First time user can create a new account by selecting the **Create New Account**. The FDA warning banner is also provided on the FDA home page.

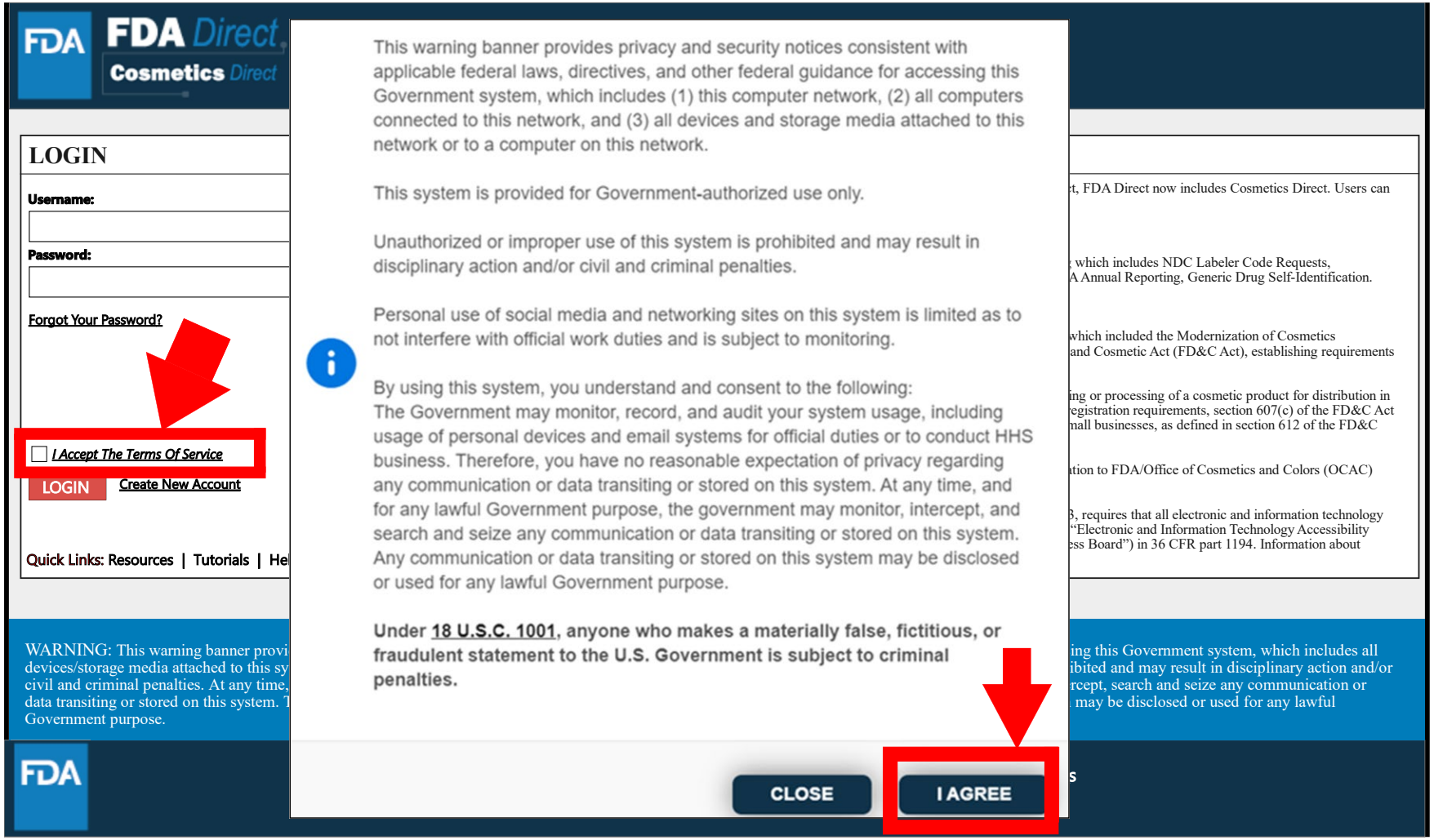
Create a New Account

There are three types of account that can be created: CDER Direct, COSMETICS Direct, and both (CDER Direct & COSMETICS Direct). DUNS is only a required field if you create a CDER Direct account or both (CDER Direct and COSMETICS Direct) account. DUNS is NOT required if you create only a COSMETICS Direct account. The system will streamline submissions to save time for the user who has drugs as well as cosmetics to choose both (CDER Direct & COSMETICS Direct) under one functional account.



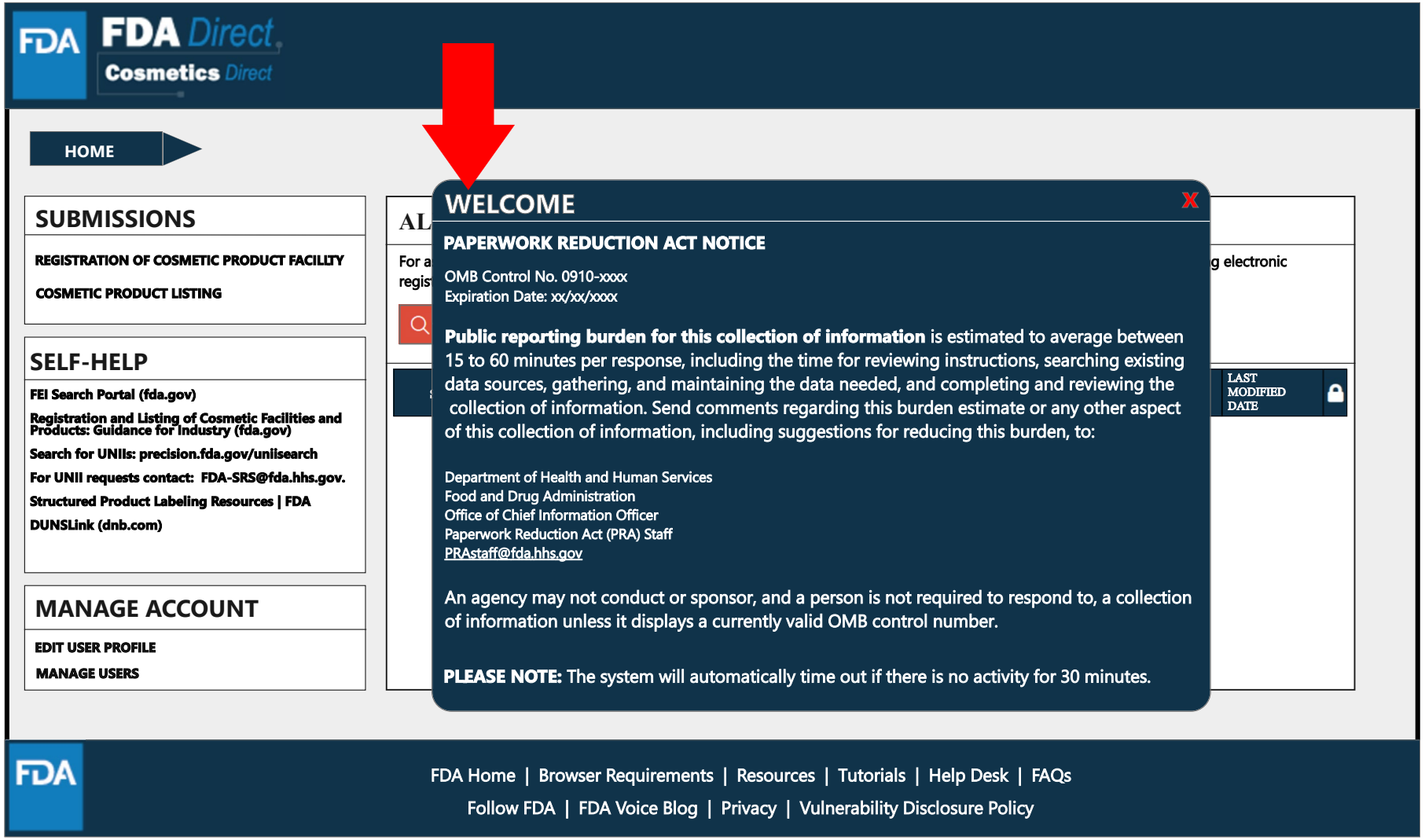
Terms of Service

Before logging into the, the user will have to agree to the terms of service by selecting **I AGREE** that will pop-up upon selecting ***I accept the terms of service***.



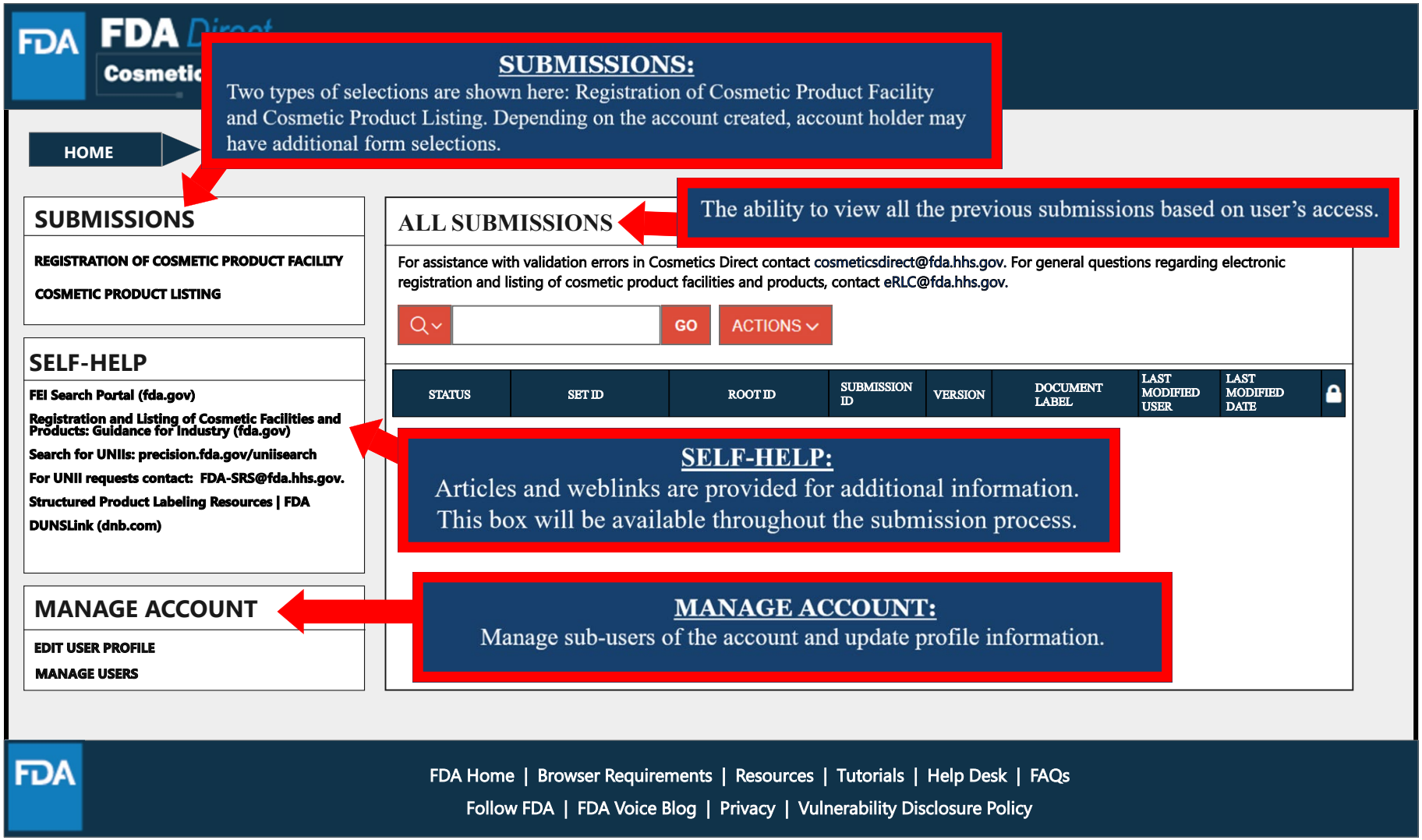
Home Page Welcome Pop-Up

A burden statement and standard PRA information will appear in the welcome pop-up each time a user logs in. (Information is a place holder subject to change)



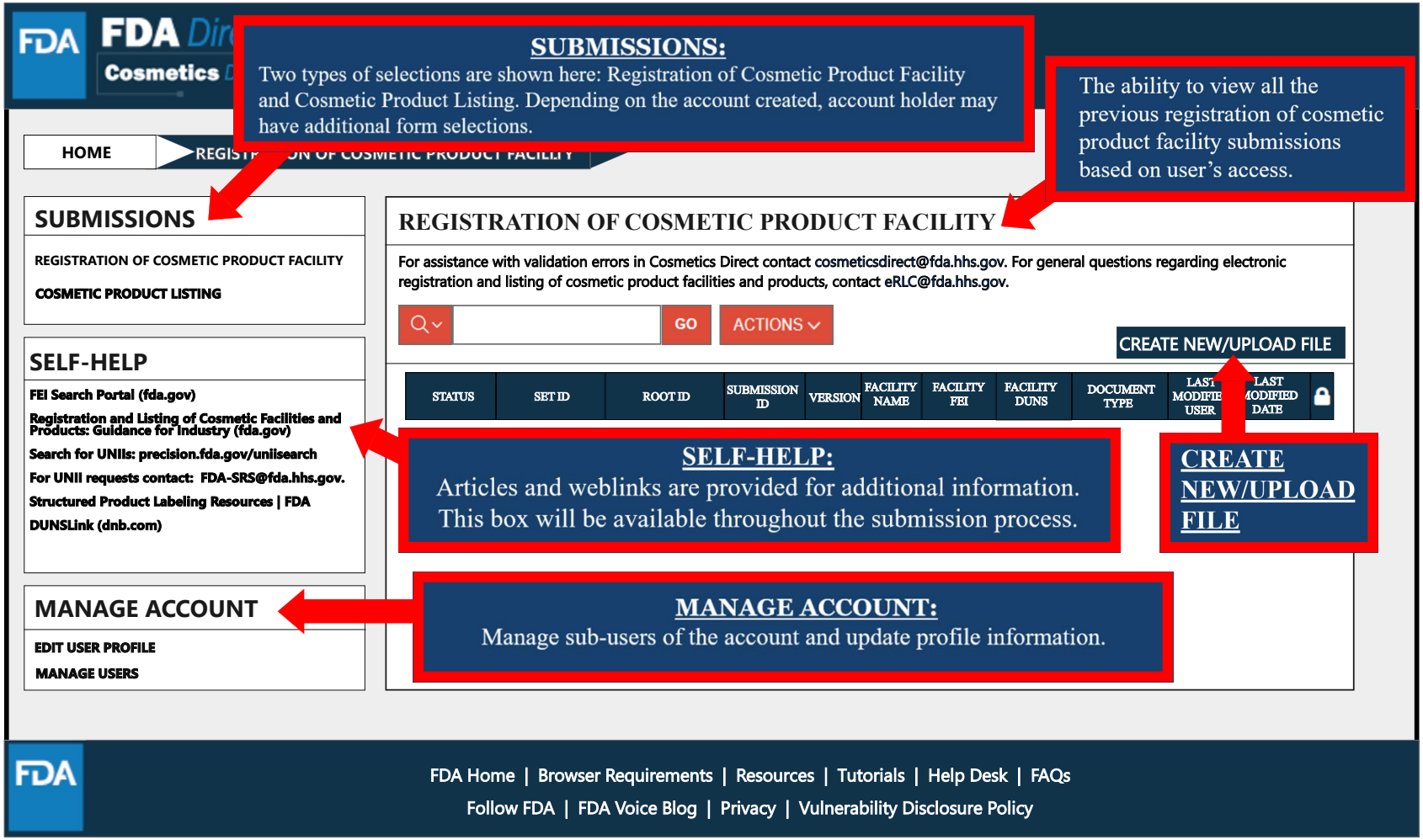
Cosmetics Direct Home Page

Home page of the Cosmetics Direct after creating an account within FDA Direct



Registration of Cosmetic Product Facility

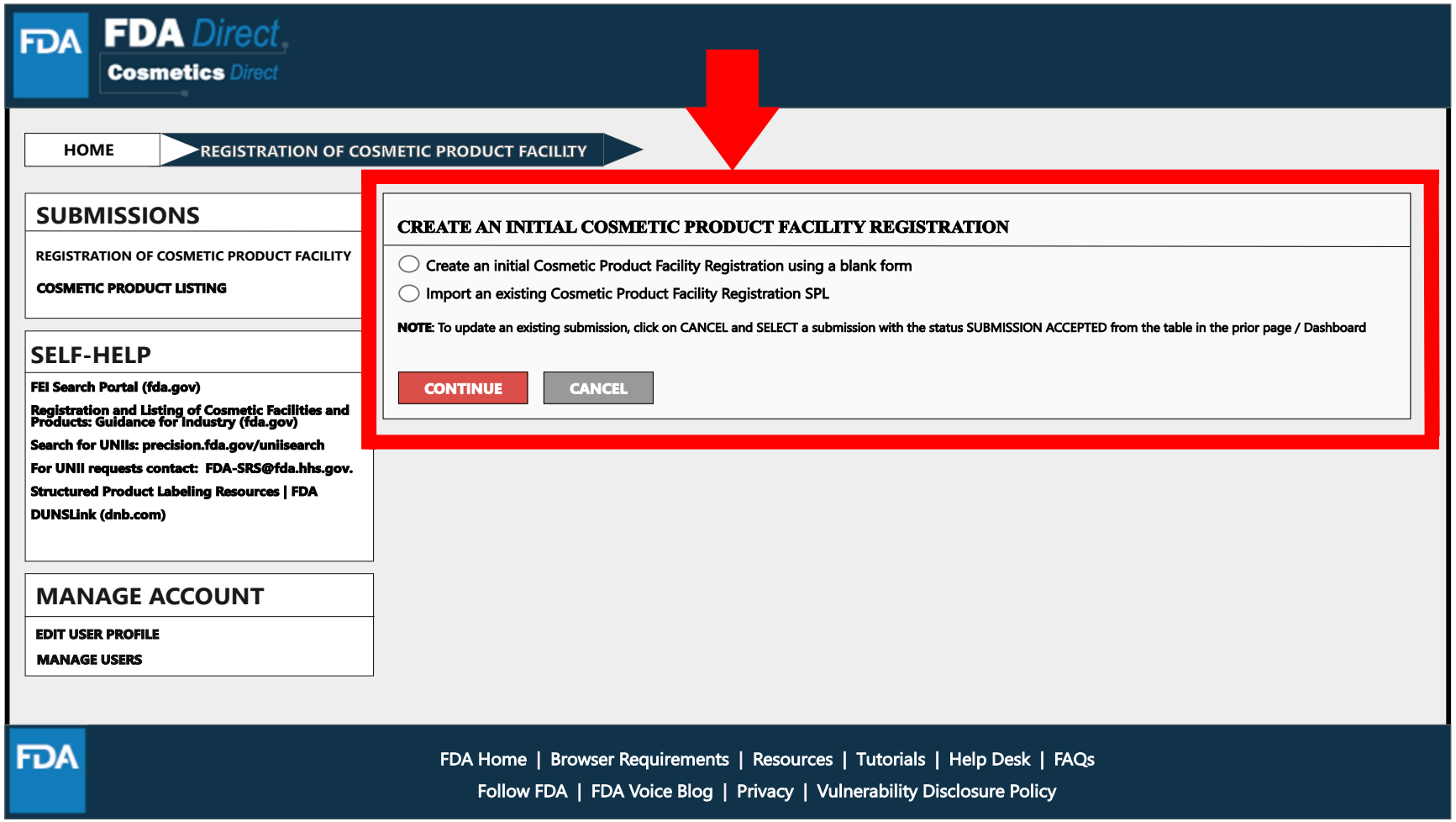
Registration of Cosmetic Product Facility Home Page



Create a New Registration or Upload an Existing File

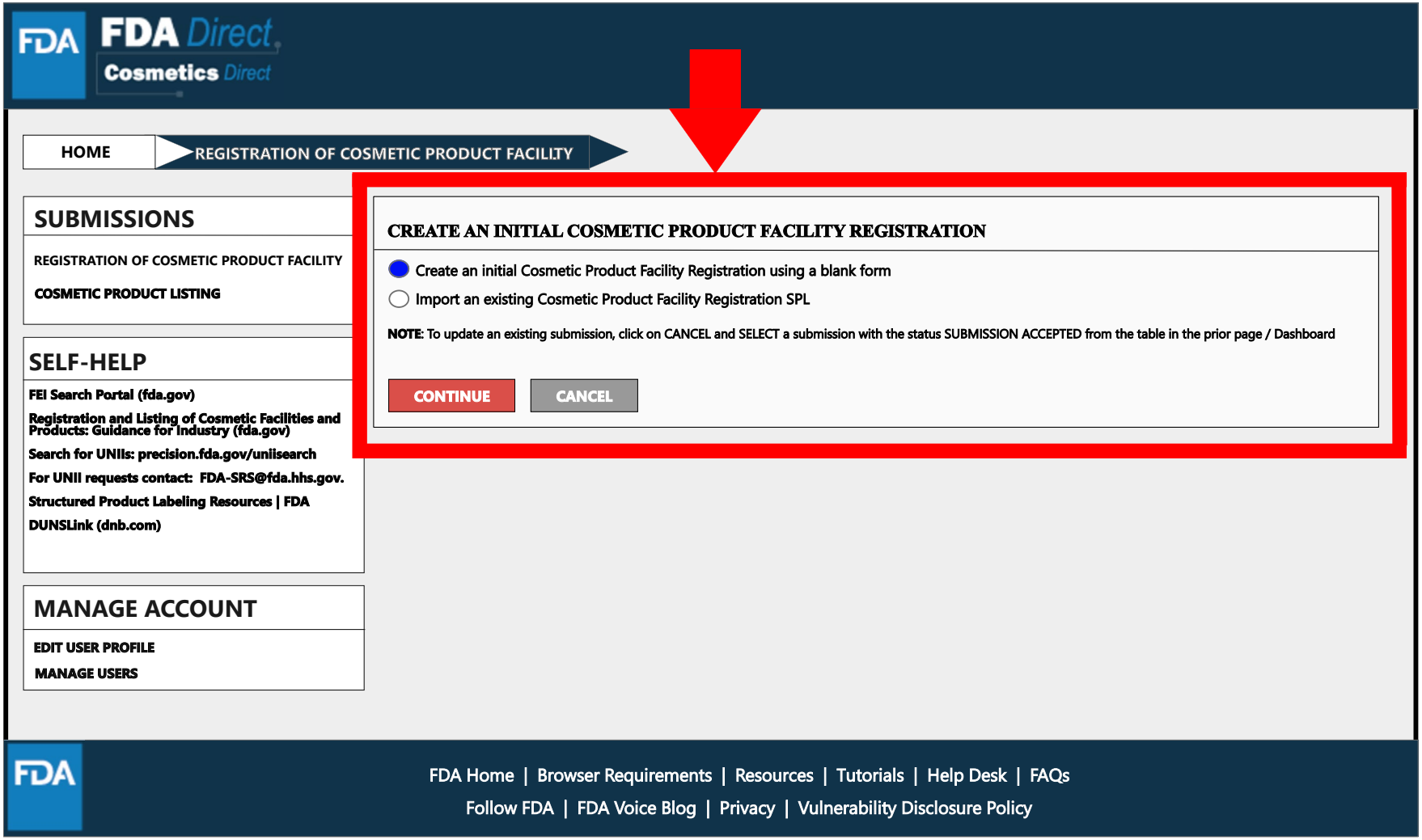
Create a New Registration or Upload an Existing File

Selecting the **CREATE NEW/UPLOAD FILE box**, from the **Registration of Cosmetic Product Facility home page** will direct user to this page with an option of creating an initial Cosmetic Product Facility Registration using a blank form or importing an FDA-accepted SPL stored on your computer in a valid XML zip file. SPL (Structured Product Labeling) is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product and facility information. Importing an existing Cosmetic Product facility registration SPL will be beneficial for bulk submission.



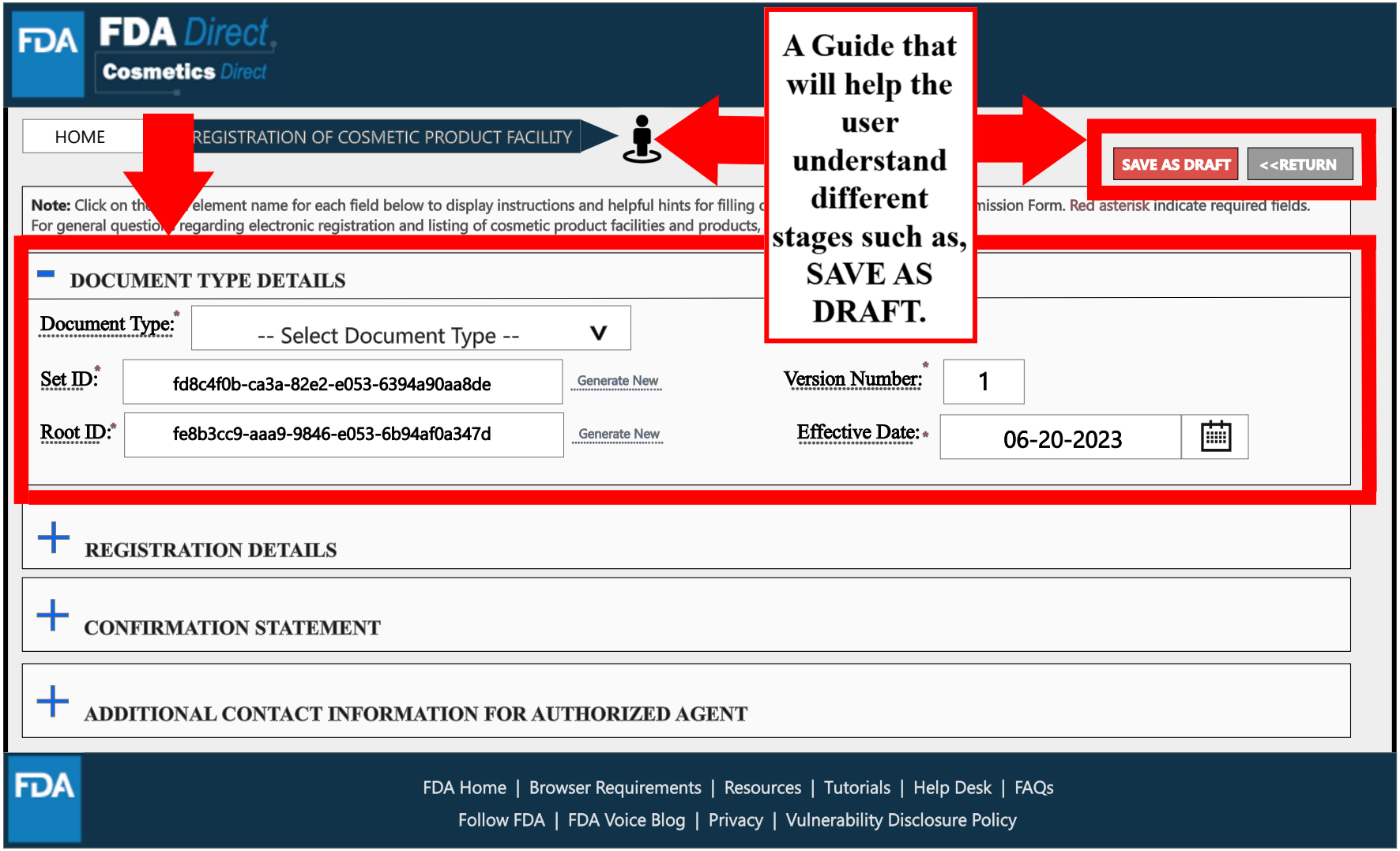
Create a New Product Facility Registration

Create an Initial Cosmetic Product Facility Registration using a blank form.

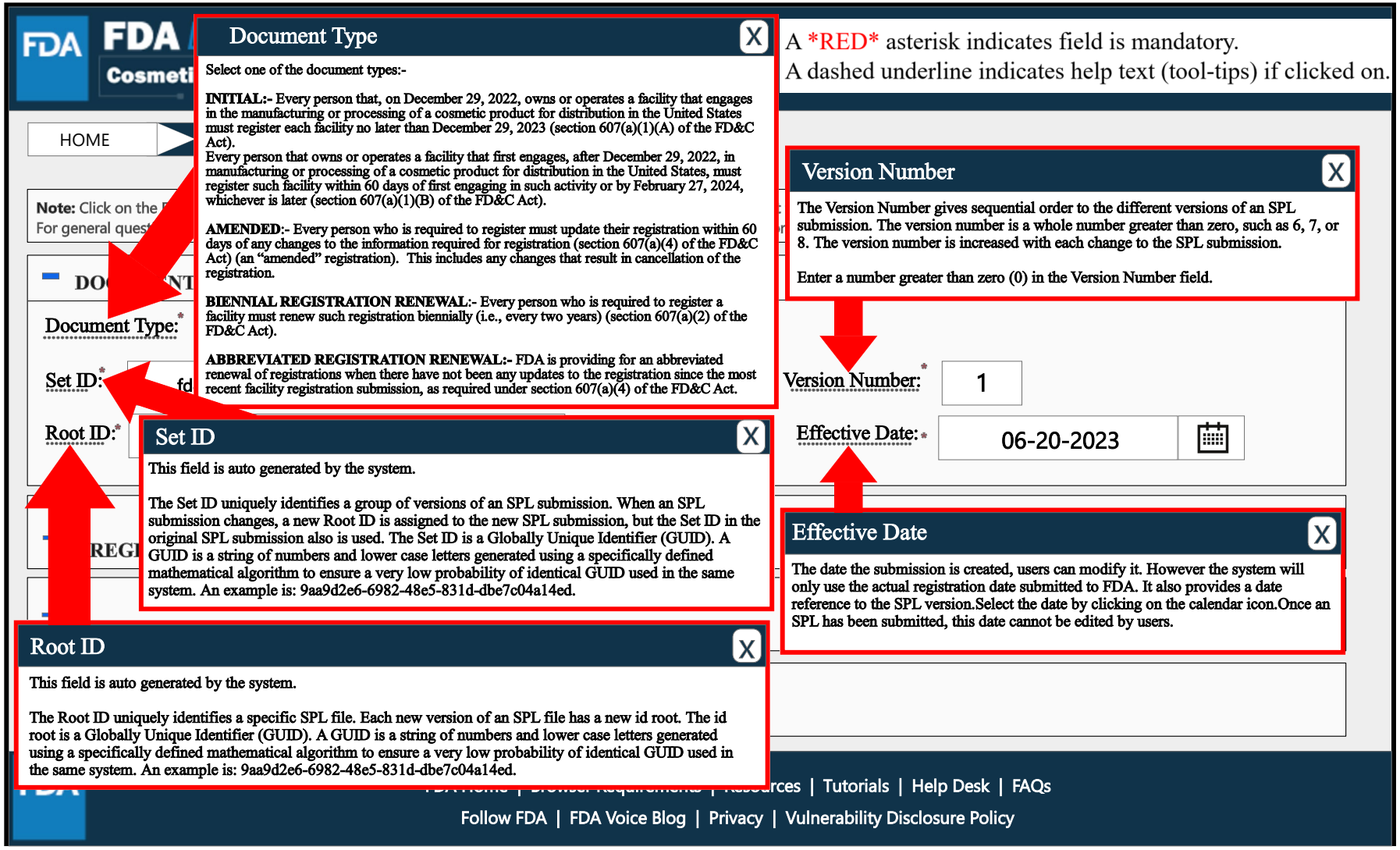


Document Type Details

Set ID and Root ID are auto-generated, and the Effective Date is the date the submission is created, but users can modify it. Once an SPL has been submitted, this date cannot be edited by users.

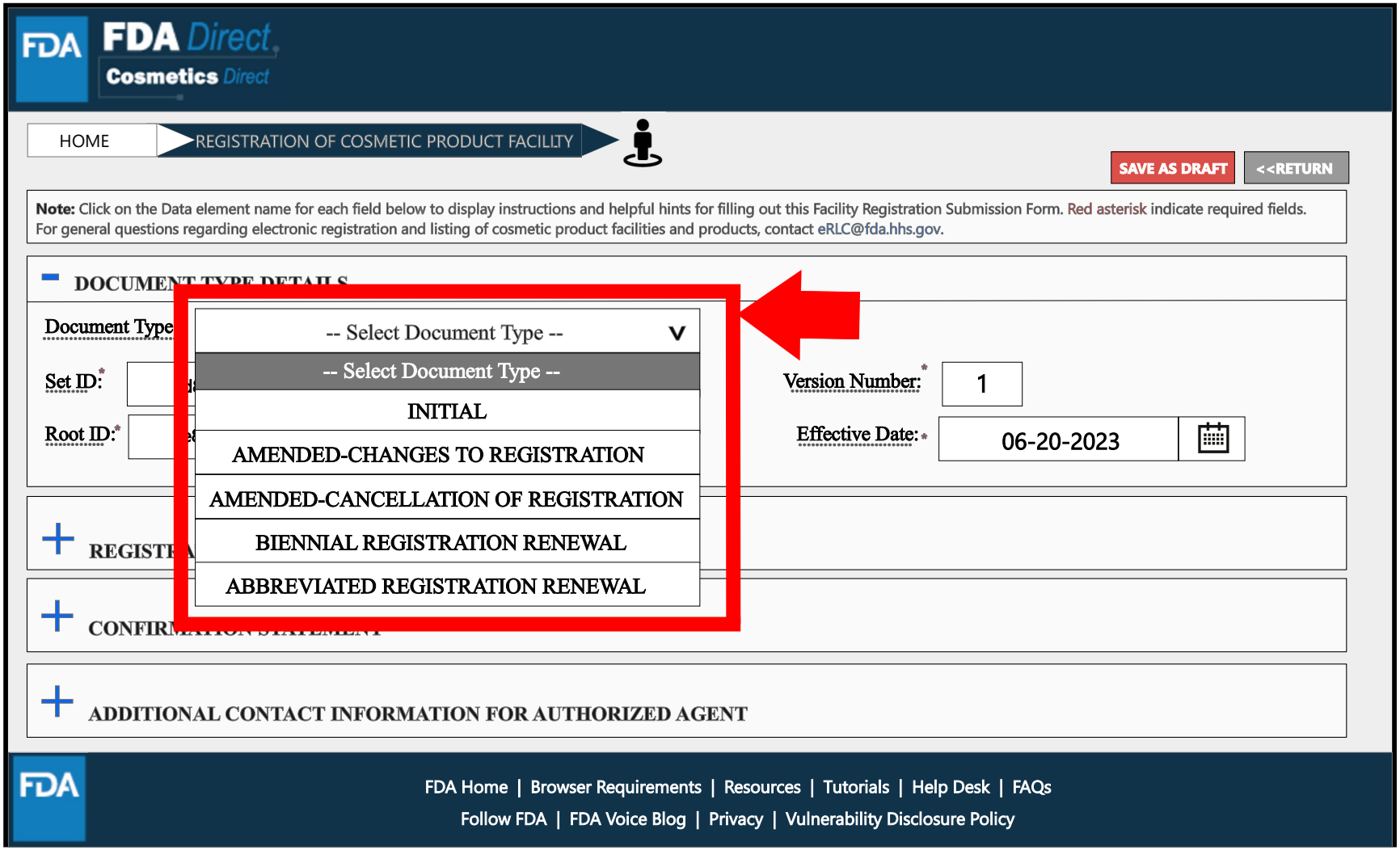


Document Type Tool Tips



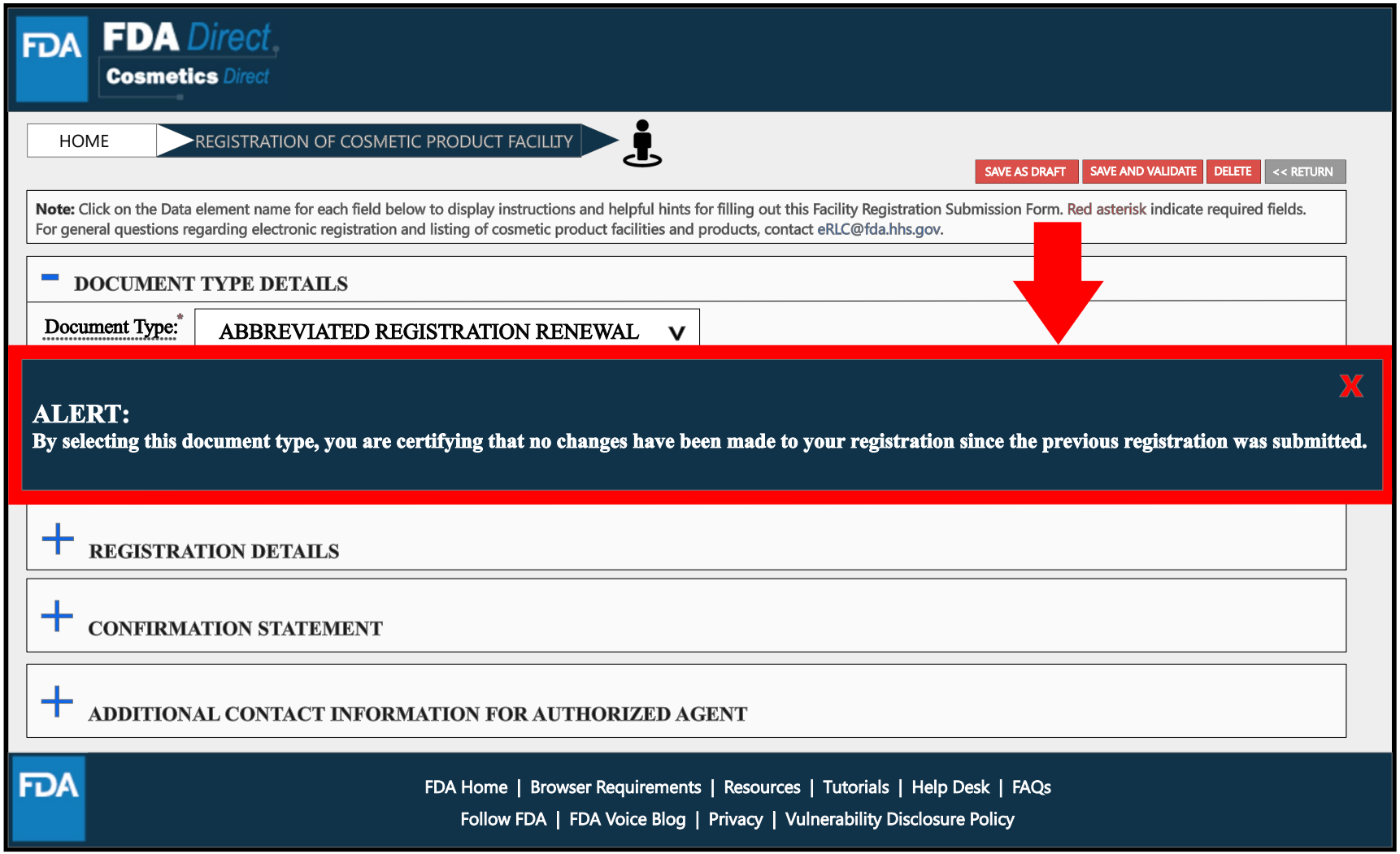
Document Type Details

By selecting the drop-down (v), five document type options will appear; initial, amended-changes to registration, amended-cancellation of registration, biennial registration renewal, and abbreviated registration renewal. (First time users will only have INITIAL as an option)



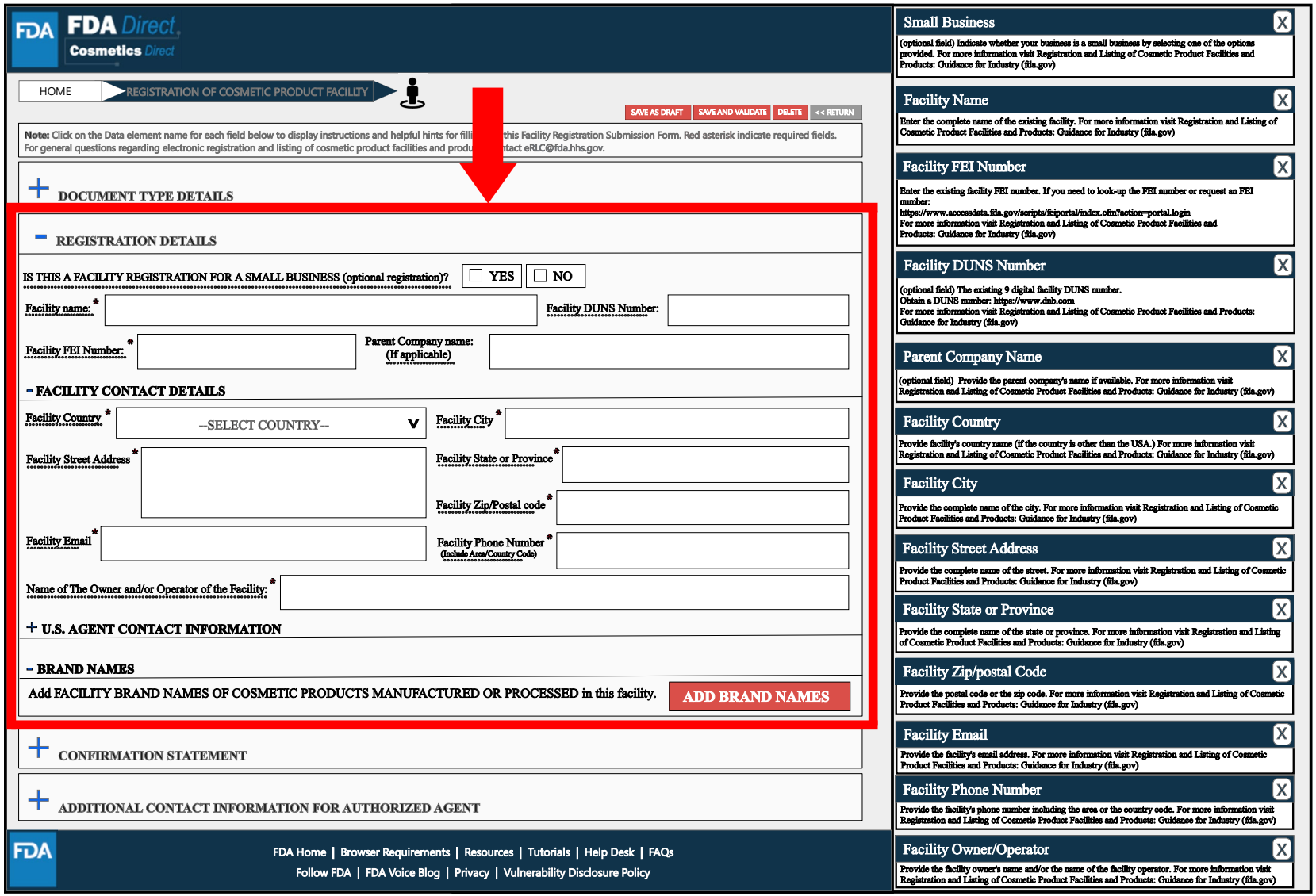
Document Type Details

Depending on which document type is selected, an ALERT box will appear, "*By selecting this document type, you are certifying that no changes have been made to your registration since the previous registration was submitted*".



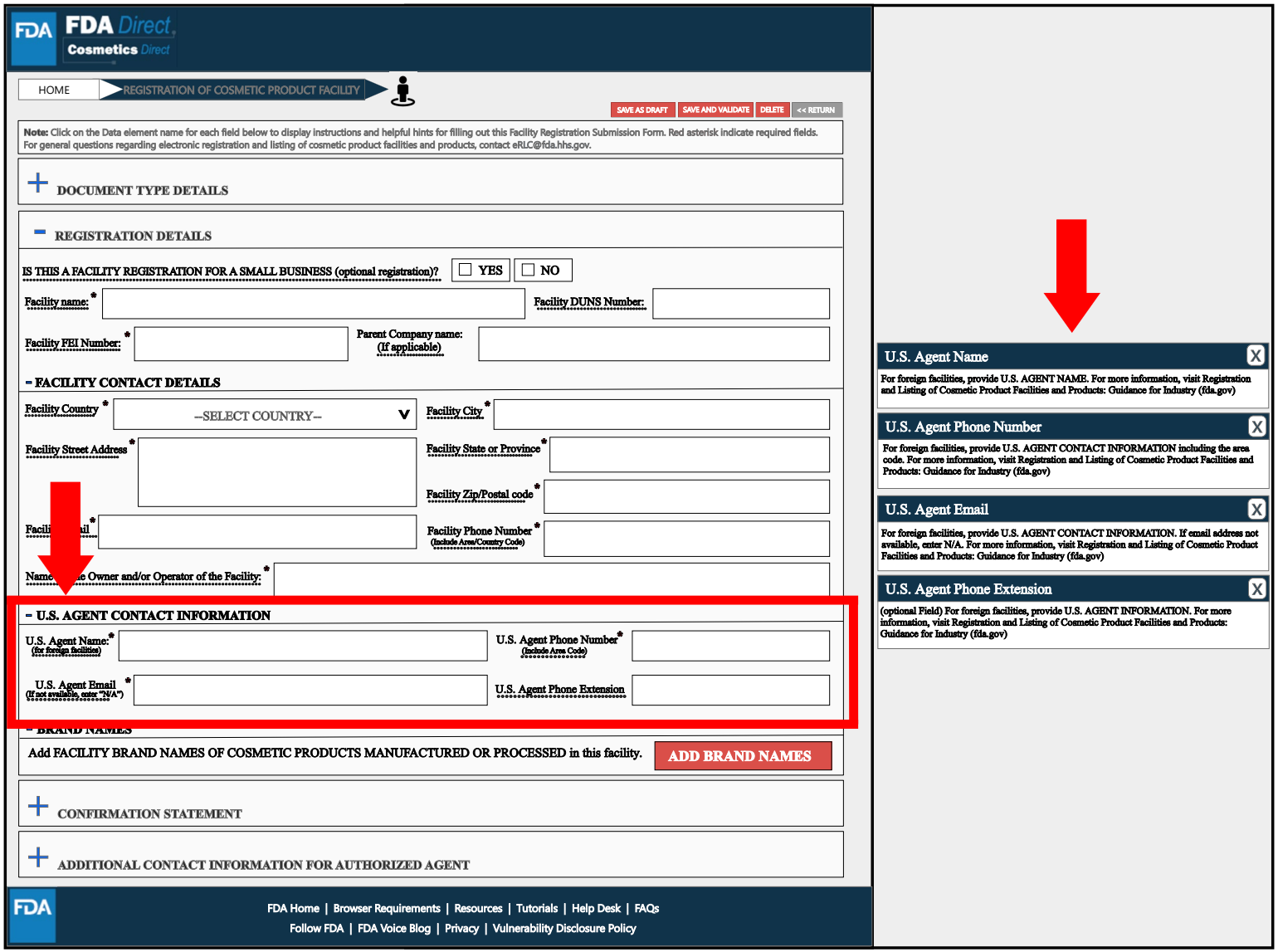
Registration Details

A *RED* asterisk indicates field is mandatory. A dashed underline indicates help text (tool-tips) if clicked on, as listed below. A link is also provided in the tool-tip for more information regarding the registration and listing of cosmetic product facilities and products.



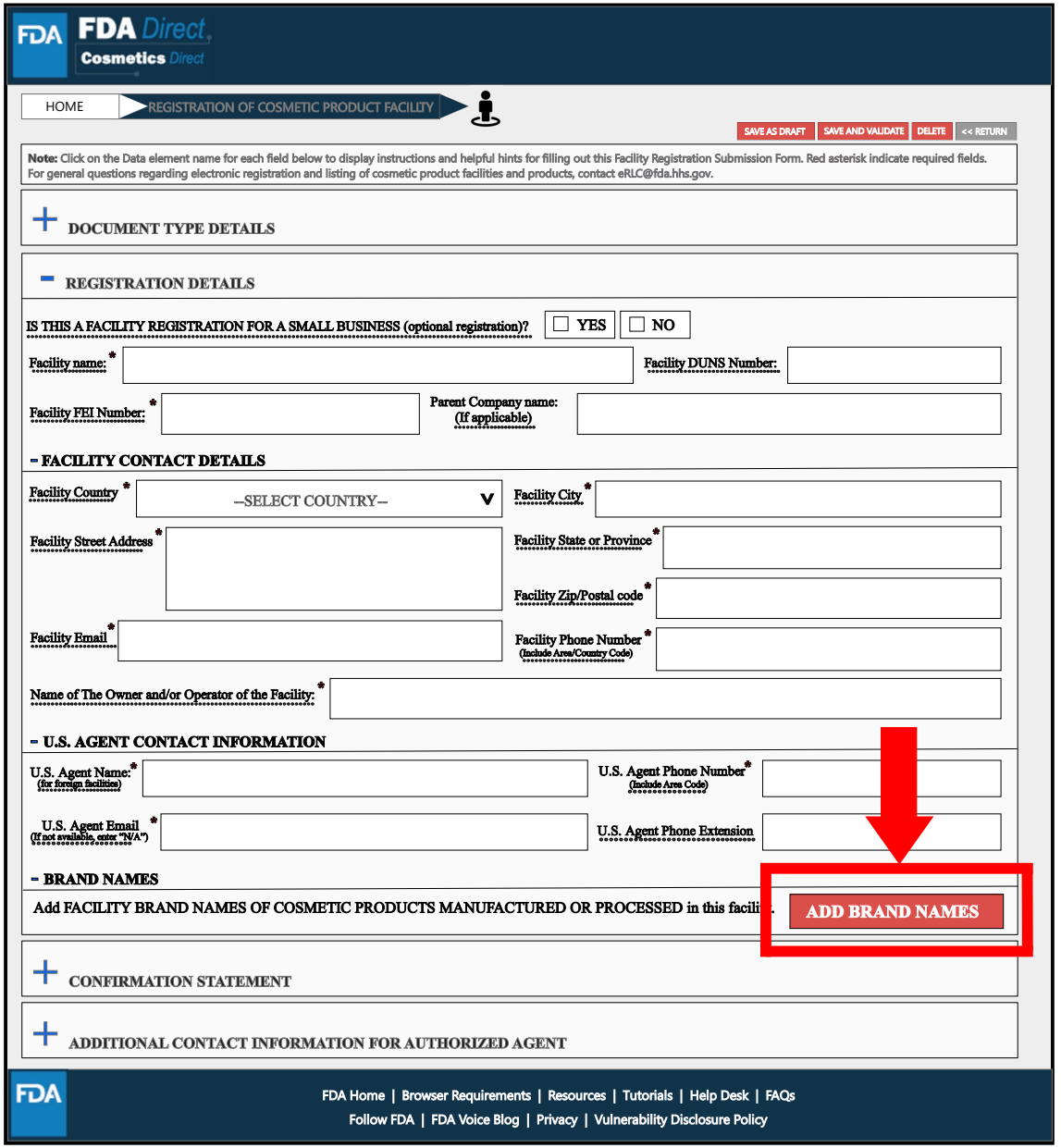
Registration Details

By selecting a country outside the U.S., the U.S. AGENT CONTACT INFORMATION will be needed.
A dashed underline indicates help text (tool-tips) if clicked on, as listed below.



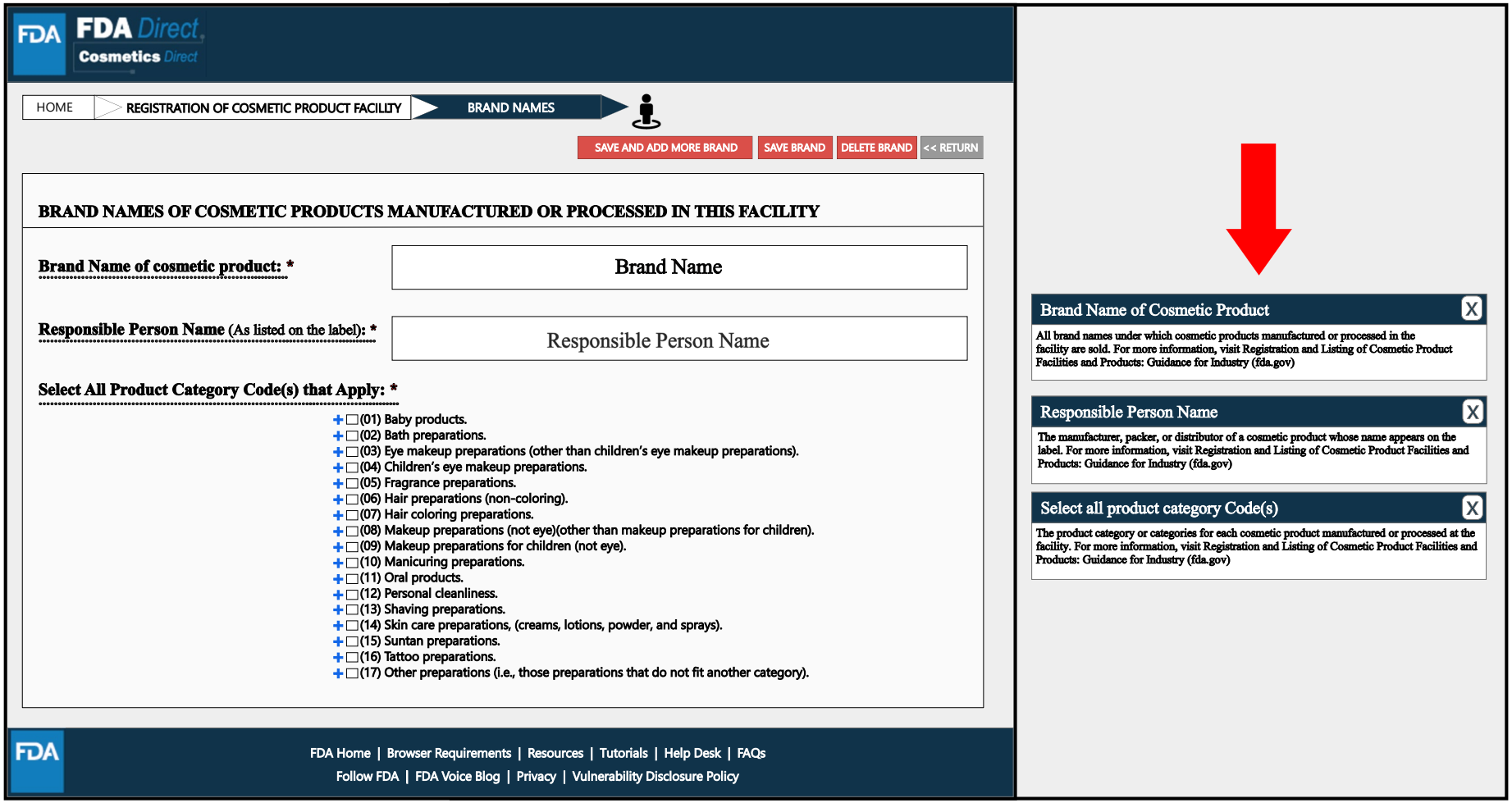
Brand Name(s)

Add Brand Names of cosmetic products manufactured or processed at this facility by selecting **ADD BRAND NAMES**.

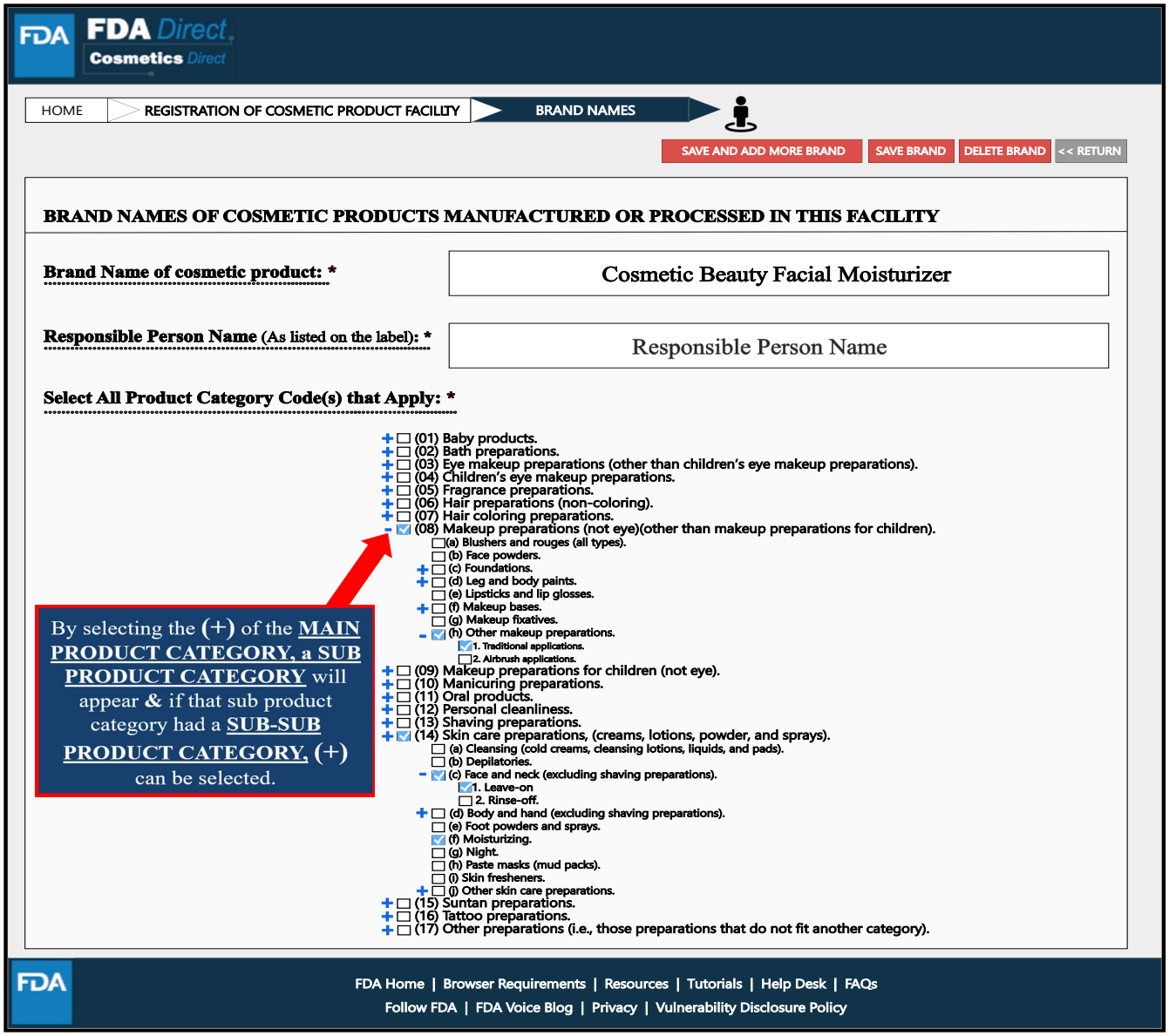


Brand Name(s) of Cosmetic Product(s) Manufactured or Processed in this Facility

Multiple Brand Names can be submitted by selecting **SAVE AND ADD MORE BRAND**. Select all the Category Code(s) that applies to this Brand Name. A dashed underline indicates help text (tool-tips) if clicked on, as listed below.

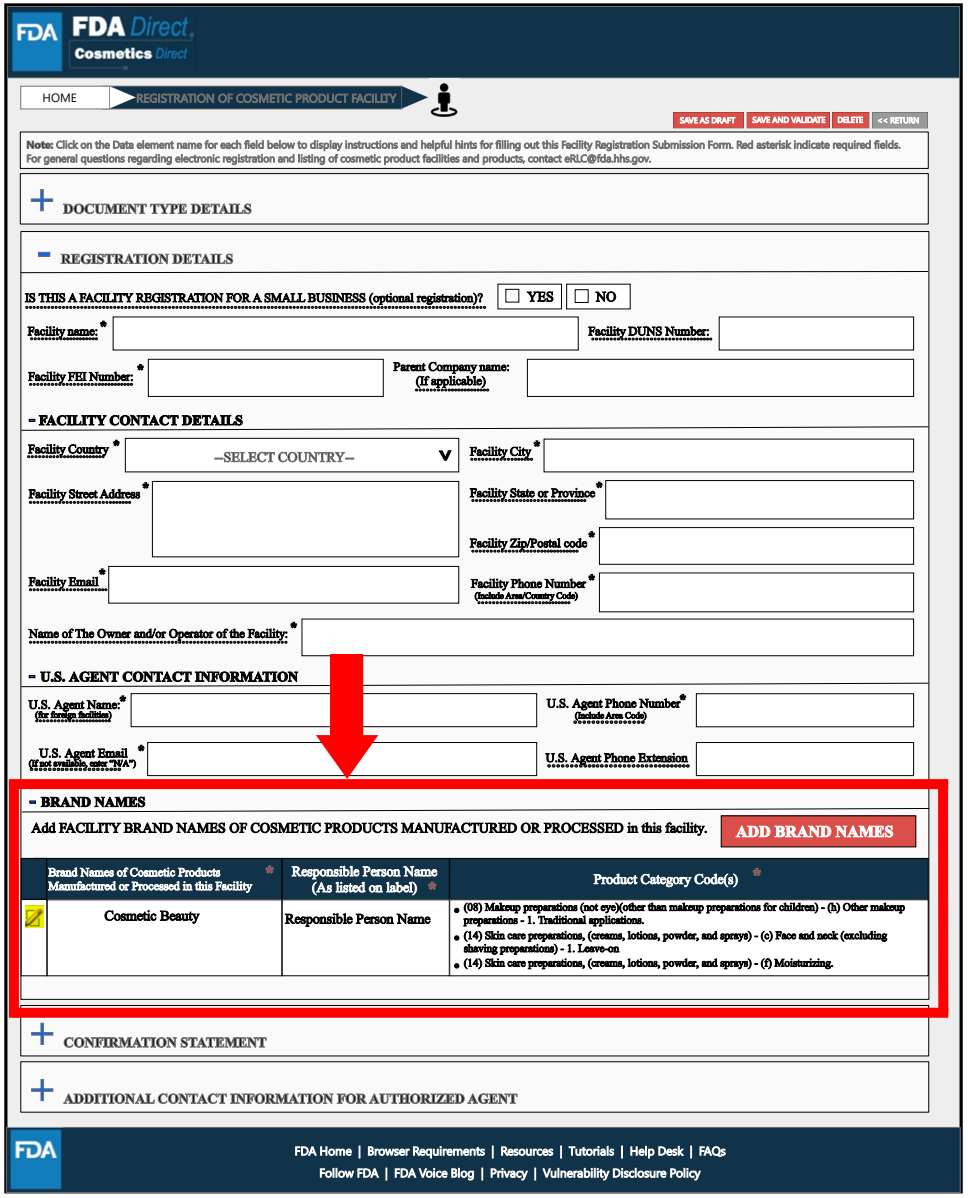


Brand Name(s) of Cosmetic Product(s) Manufactured or Processed in this Facility (Example)



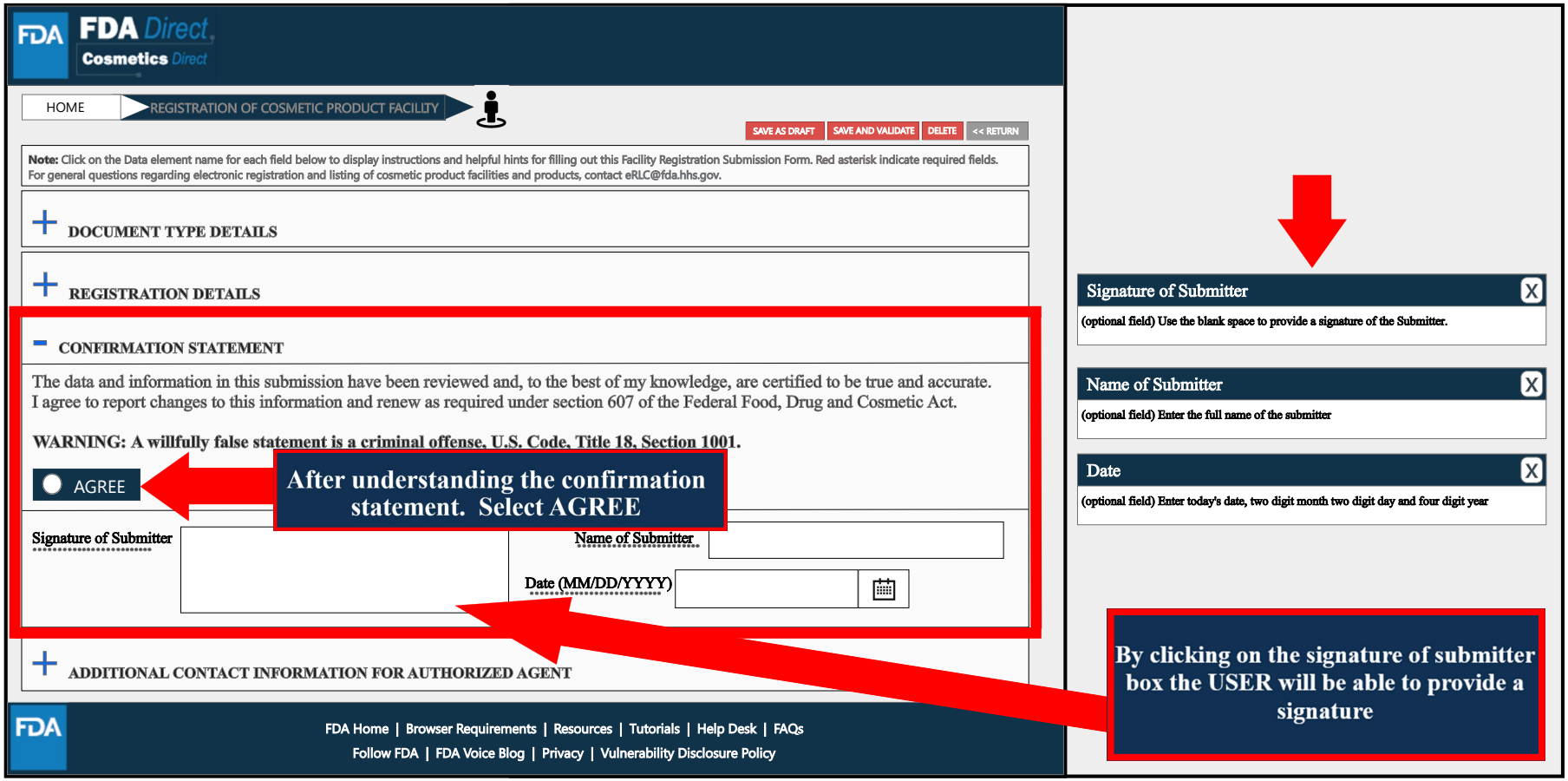
Brand Name of Cosmetic Product Manufactured or Processed in this Facility (Example)

The information that was provided in the BRAND NAME TAB will appear under BRAND NAMES.



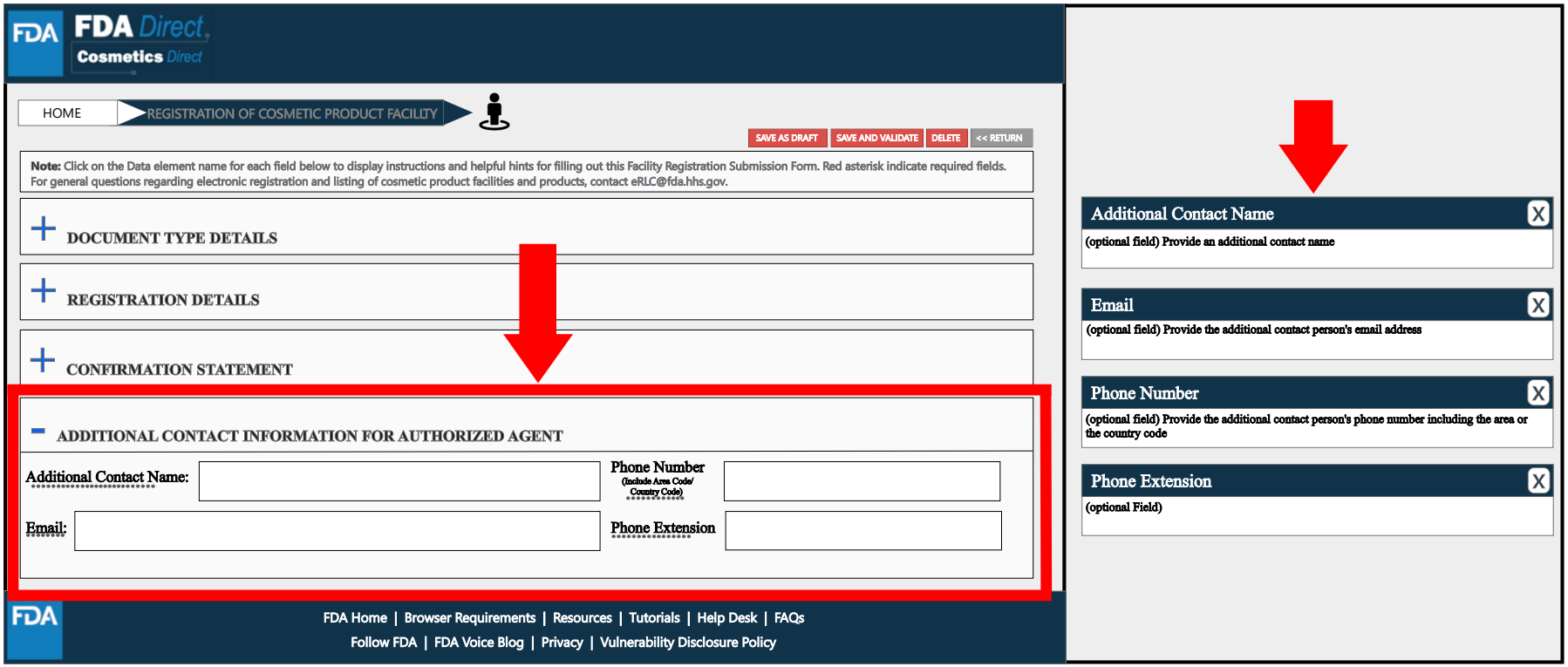
Confirmation Statement

A dashed underline indicates help text (tool-tips) if clicked on, as listed below.



Additional Contact Information for Authorized Agent

A dashed underline indicates help text (tool-tips) if clicked on, as listed below.

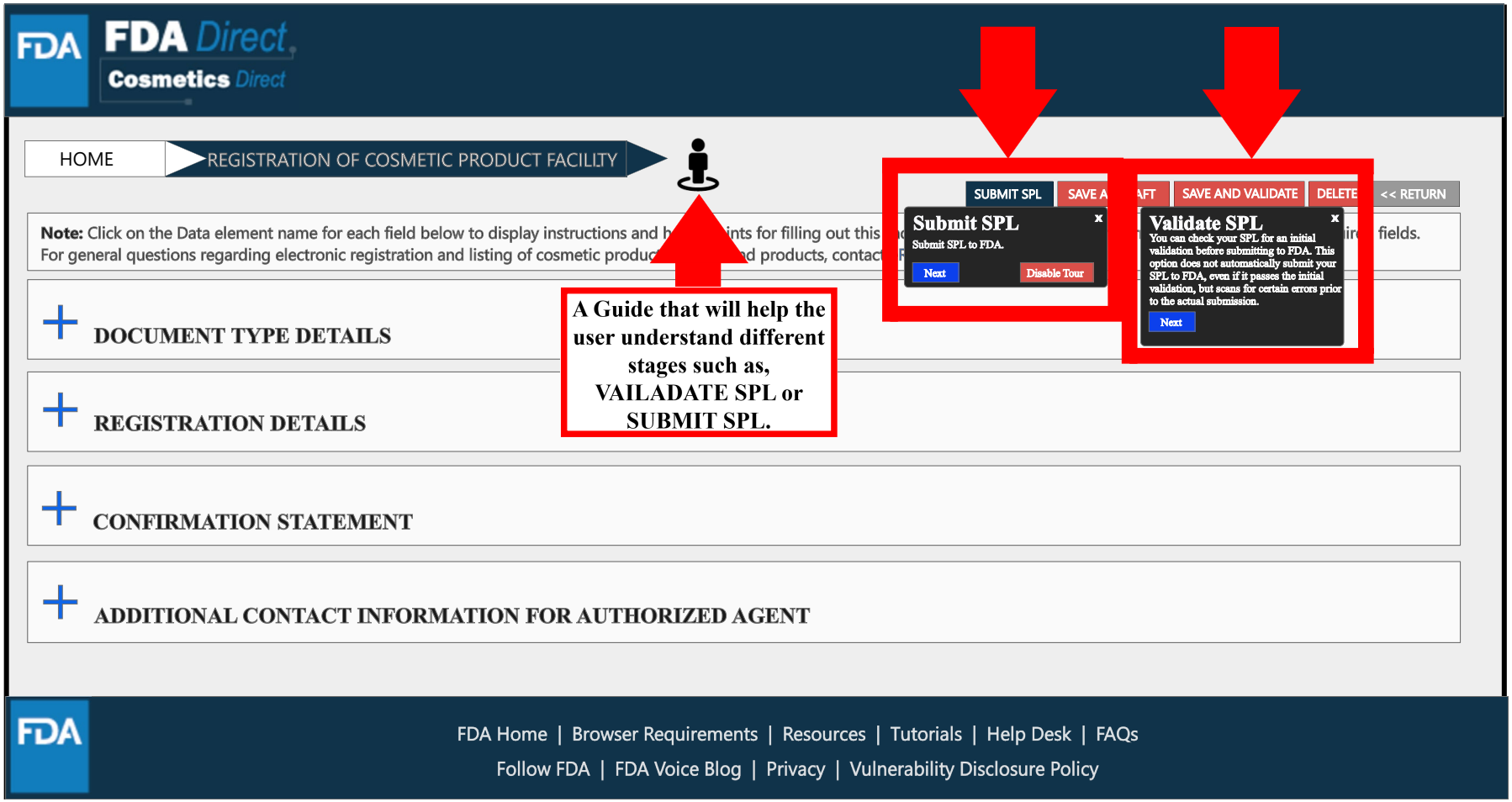


Completed

After filling in all the required information, **SAVE AND VALIDATE**, to identify any errors.

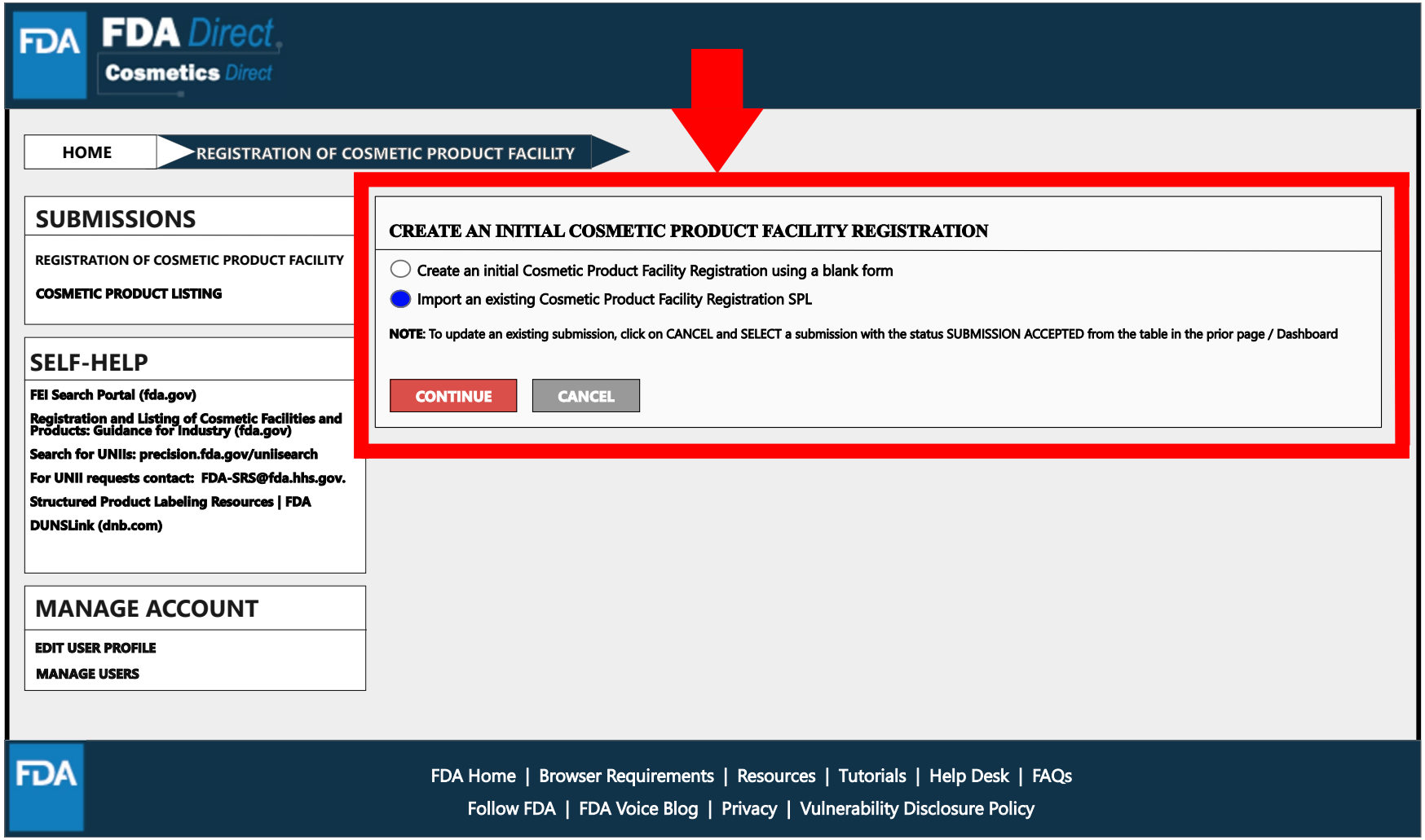
OR

Select **SUBMIT SPL** for the form to be submitted to FDA.



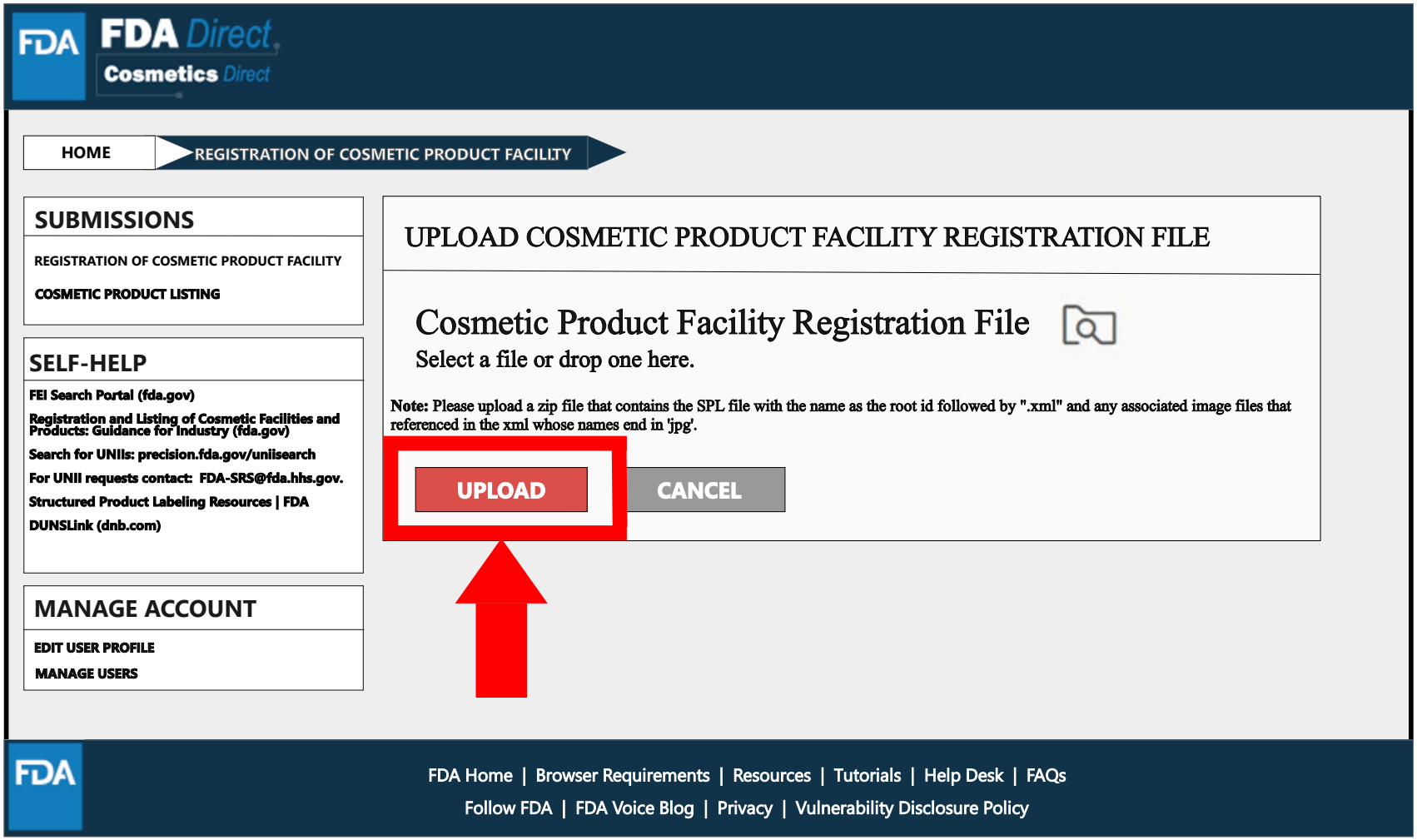
Upload a File

In order to upload a file, select **Import an existing Cosmetic Product Facility Registration SPL**. Importing an existing Cosmetic Product Facility Registration SPL will be beneficial for bulk submission.



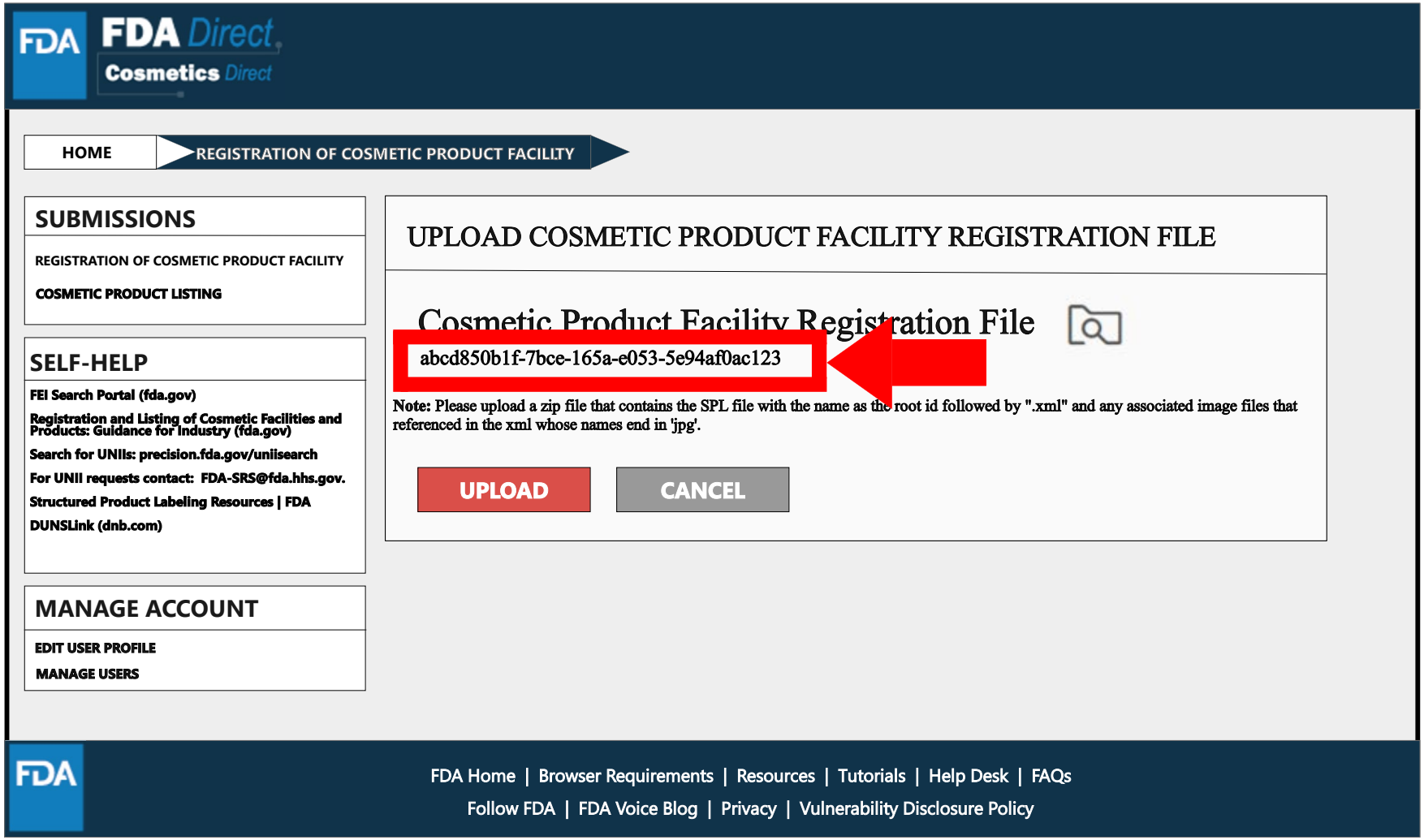
Upload a File

User will be able to upload a pre-existing ZIP FILE. This file may contain both the xml file and image (jpg) files. SPL(Structured Product Labeling) is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product and facility information. For more information regarding SPL, utilize the **Structured Product Labeling Resources** (SPL) link provided under **SELF-HELP**.



Upload a File (Example)

An example to what a zip file could be, may contain .xml file and image (jpg) files.



Zip File (Example)

An example to what an XML format could look like.

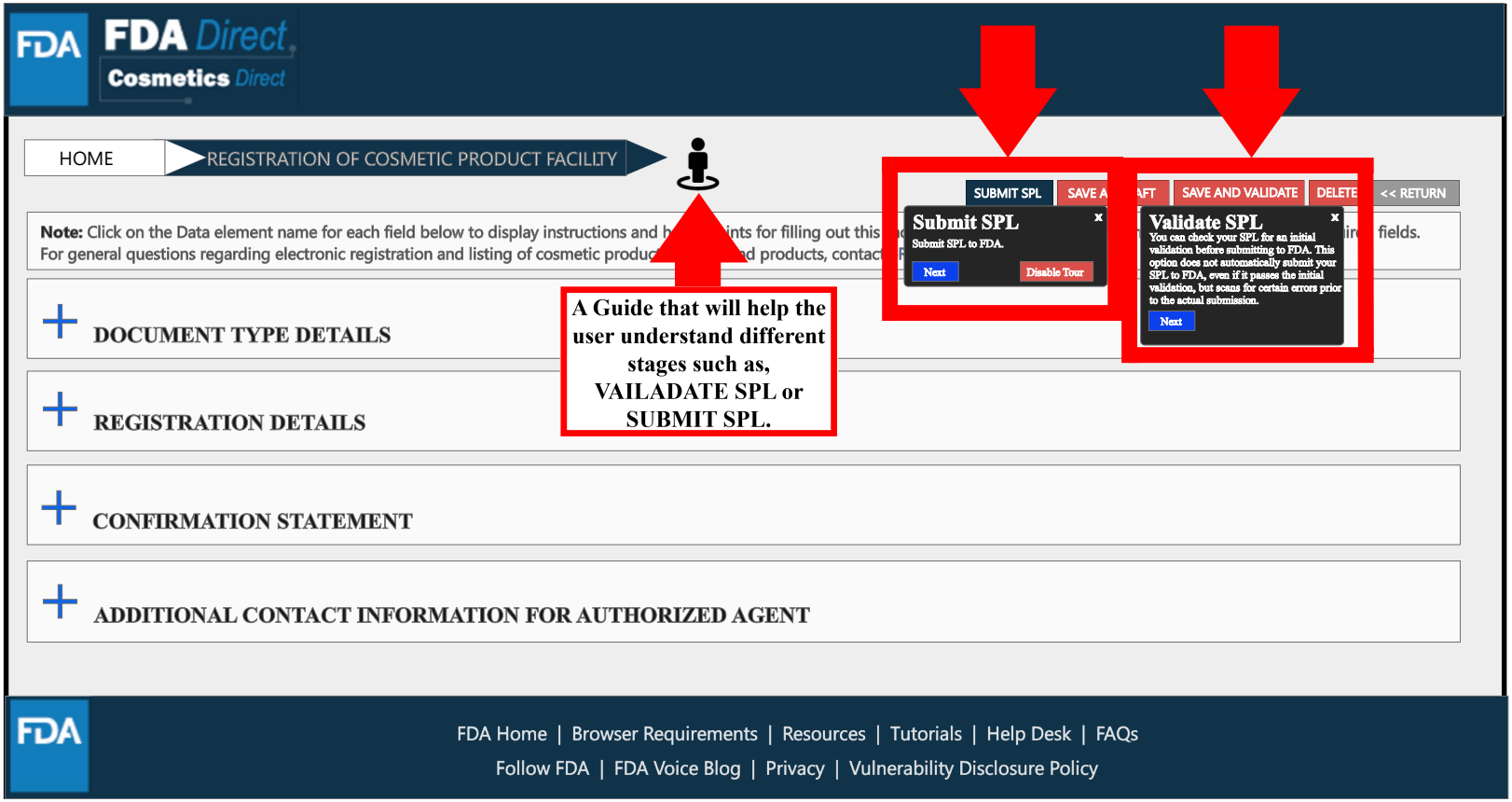
```
<?xml version="1.0" encoding="UTF-8"?>
<?xml-stylesheet href="https://www.accessdata.fda.gov/spl/stylesheet/spl.xsl" type="text/xsl"?>
<document xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:schemaLocation="urn:hl7-org:v3 https://www.accessdata.fda.gov/spl/schema/spl.xsd">
  <id root="fd8c4f0b-ca3b-82e2-e053-6394a90aa8de"/>
  <code code="51725-0" codeSystem="2.16.840.1.113883.6.1" displayName=" FACILITY
REGISTRATION"/>
  <effectiveTime value="[DATE]"/>
  <setId root="fd8c4f0b-ca3a-82e2-e053-6394a90aa8de"/>
  <versionNumber value="1"/>
  <author>
   <time/>
   <assignedEntity>
    <representedOrganization>
     <assignedEntity>
      <assignedOrganization>
       <id root="1.3.6.1.4.1.519.1" extension="314988747"/>
       <name>[COMPANY'S NAME]</name>
       <contactParty>
        <addr>
         <streetAddressLine>[ENTRY THE STREET ADDRESS]</streetAddressLine>
         <city>[ENTRY CITY NAME]</city>
         <postalCode>[ENTRY POSTAL CODE]</postalCode>
         <country>[ENTRY COUNTRY NAME]</country>
        </addr>
        <telecom value="tel:[ENTRY PHONE NUMBER]"/>
        <telecom value="[ENTRY EMAIL ADDRESS]"/>
        <contactPerson>
         <name>[ENTRY FULL NAME]</name>
        </contactPerson>
       </contactParty>
       <assignedEntity>
```

Upload File (Example)

After **UPLOADING A FILE** (XML ZIP FILE), the system will auto-fill all the required fields and the form will be ready to **SAVE AND VALIDATE** to check for any errors. This is an easy way to submit multiple Cosmetic Product Facility Registrations under one submission ID.

VALIDATE SPL: *"You can check your SPL for an initial validation before submitting to FDA. This option does not automatically submit your SPL to FDA, even if it passes the initial validation, but scans for certain errors prior to the actual submission."*

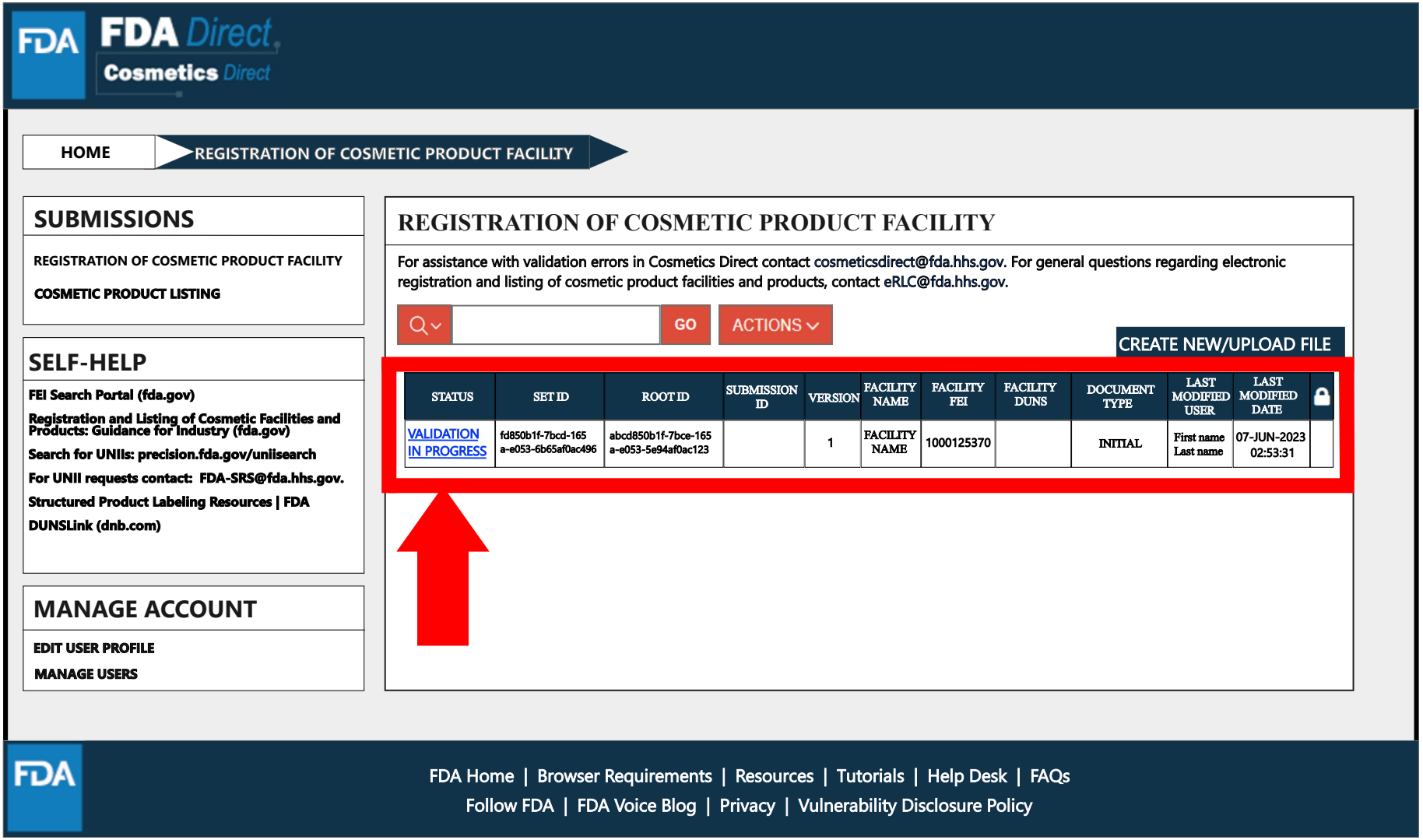
Select **SUBMIT SPL** for the form to be submitted to FDA. The Submit SPL box is a help tool that can guide a user through the process.



Registration Status Examples

Registration Status: Validation in Progress

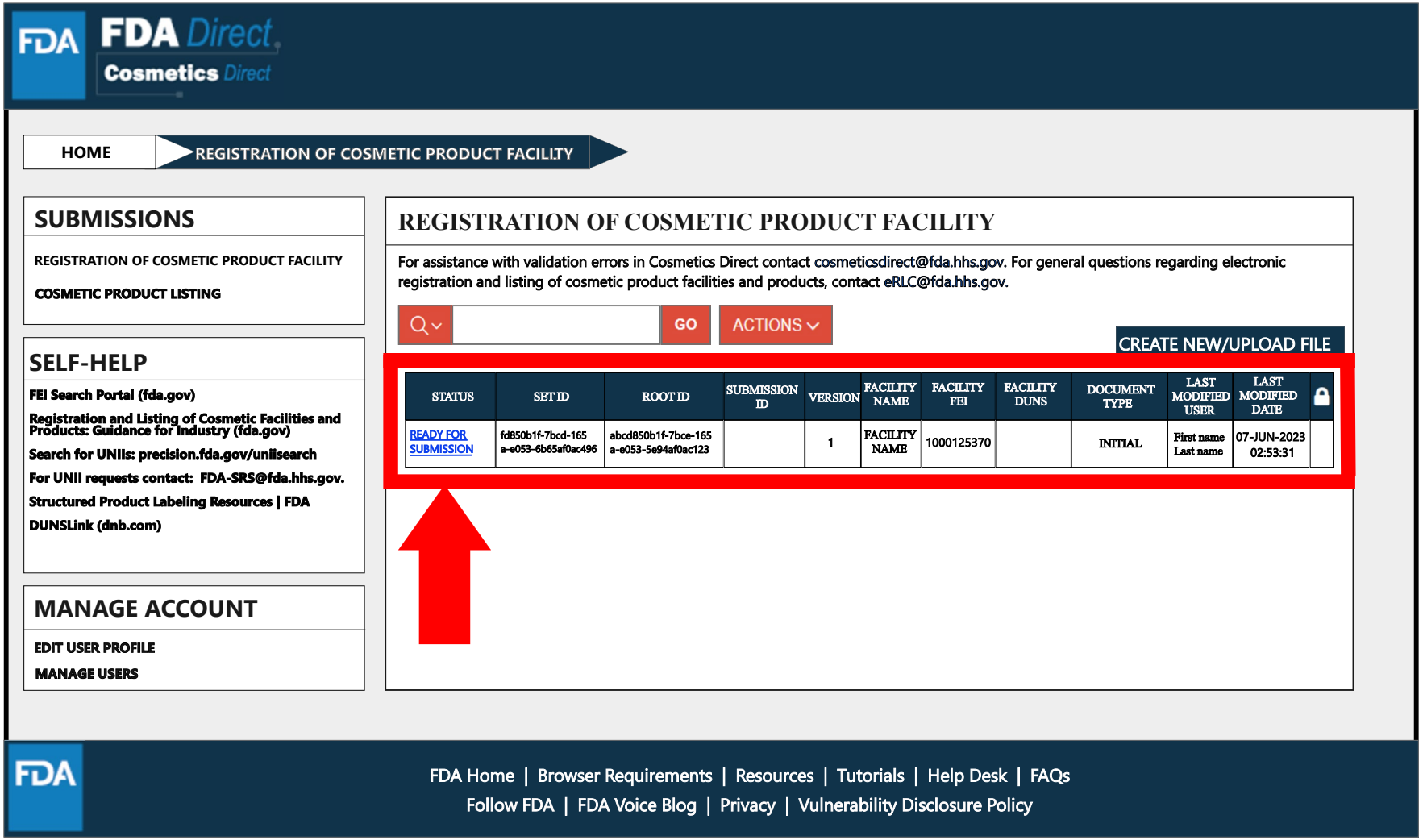
After SAVE AND VALIDATE, the registration of cosmetic product facility home page will have the following details as shown below. The status will be in **VALIDATION IN PROGRESS**.



Registration Status: Ready for Submission

VALIDATE SPL: You can check your SPL for an initial validation before submitting to FDA. This option does not automaticall submit your SPL to FDA, even if it passes the initial validation, but scans for certain errors prior to the actual submission.

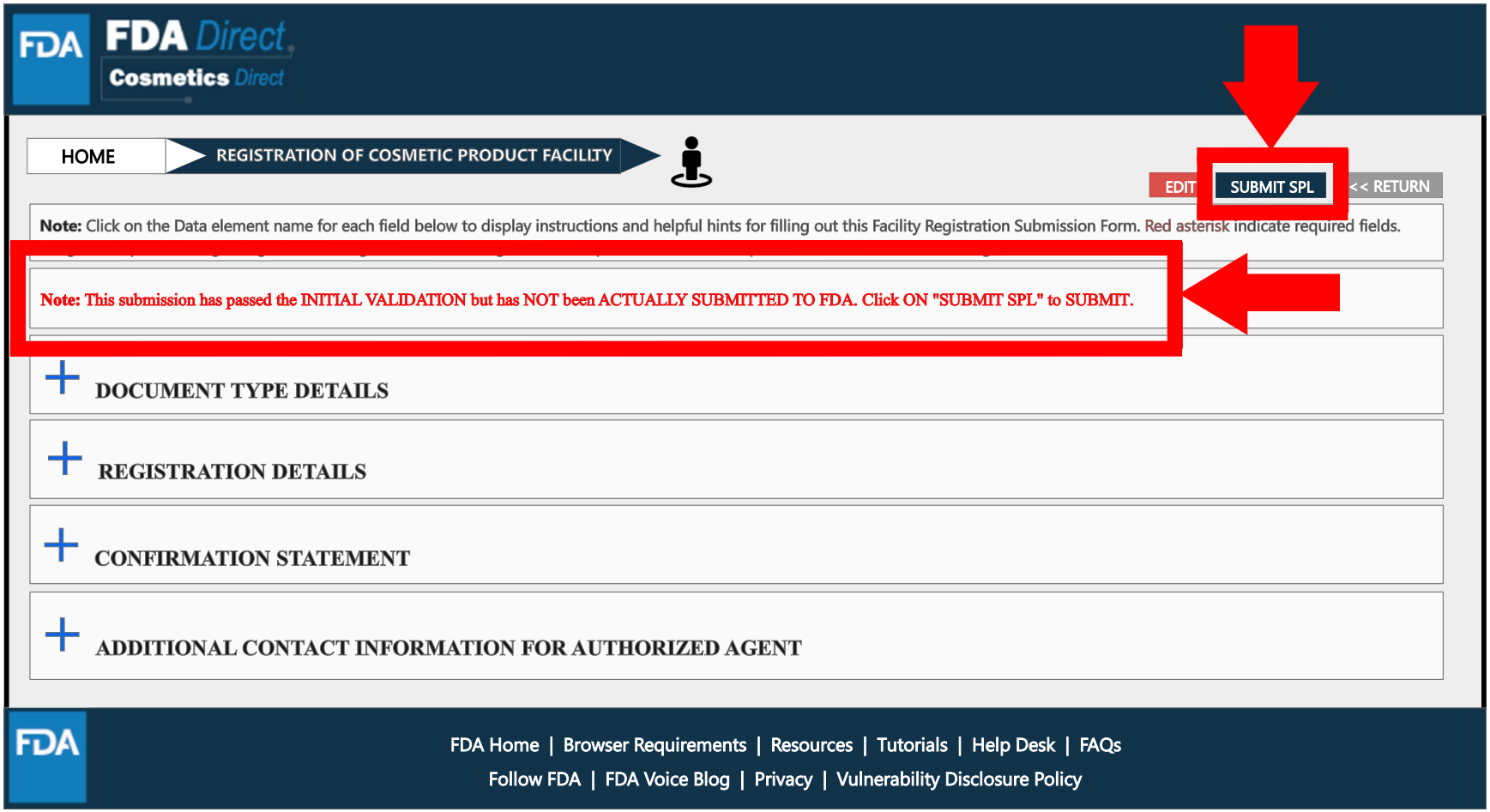
Once the system has completed a quick VALIDATION, the status **VALIDATION IN PROGRESS** will change to **READY FOR SUBMISSION**.



Registration Status: Ready for Submission to Submit SPL

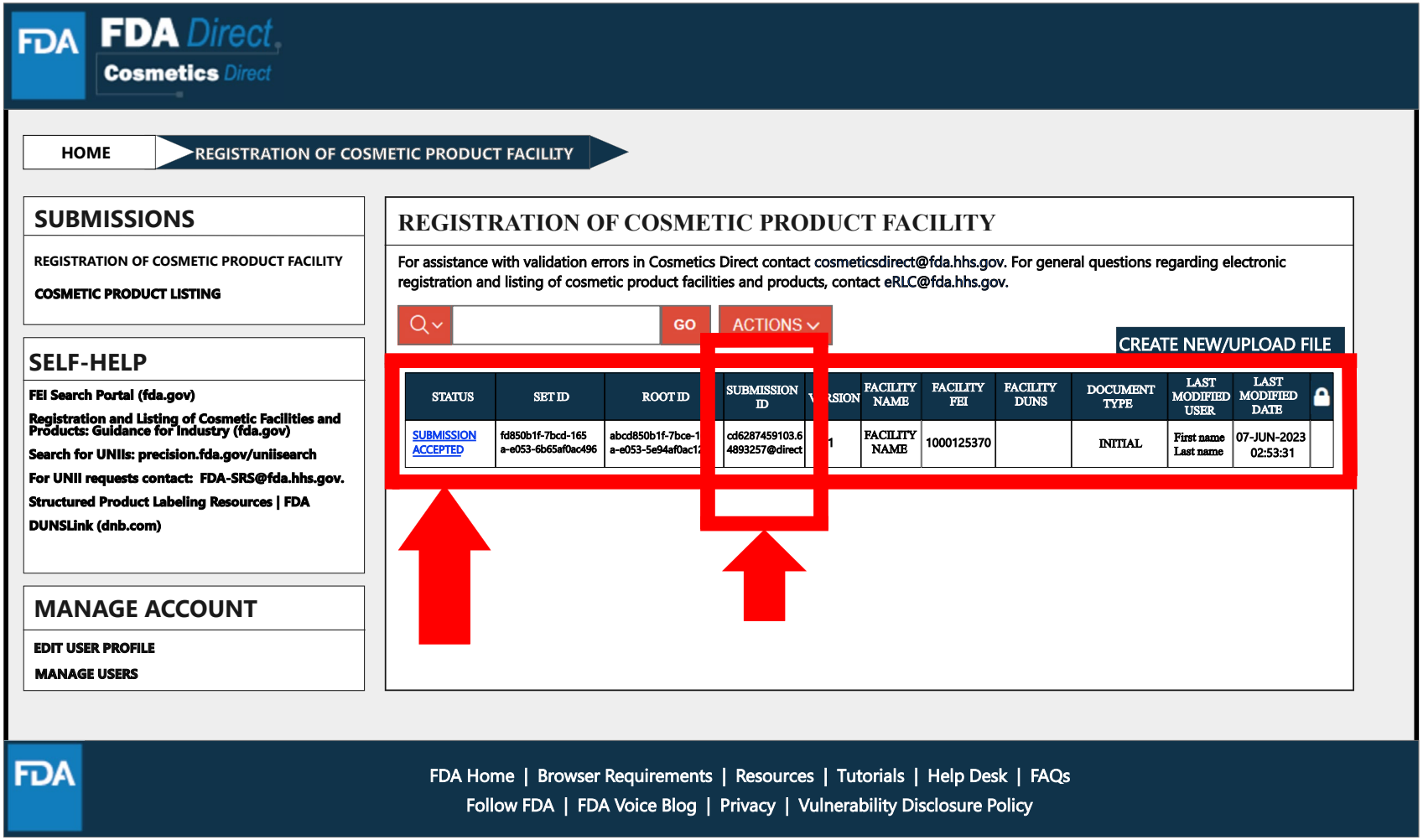
By clicking on the **READY FOR SUBMISSION**, the registration will be ready for **SUBMIT SPL**.

The system will generate a message stating that, *This submission has passed the INITIAL VALIDATION but has NOT been ACTUALLY SUBMITTED TO FDA. Click ON "SUBMIT SPL" to SUBMIT.*



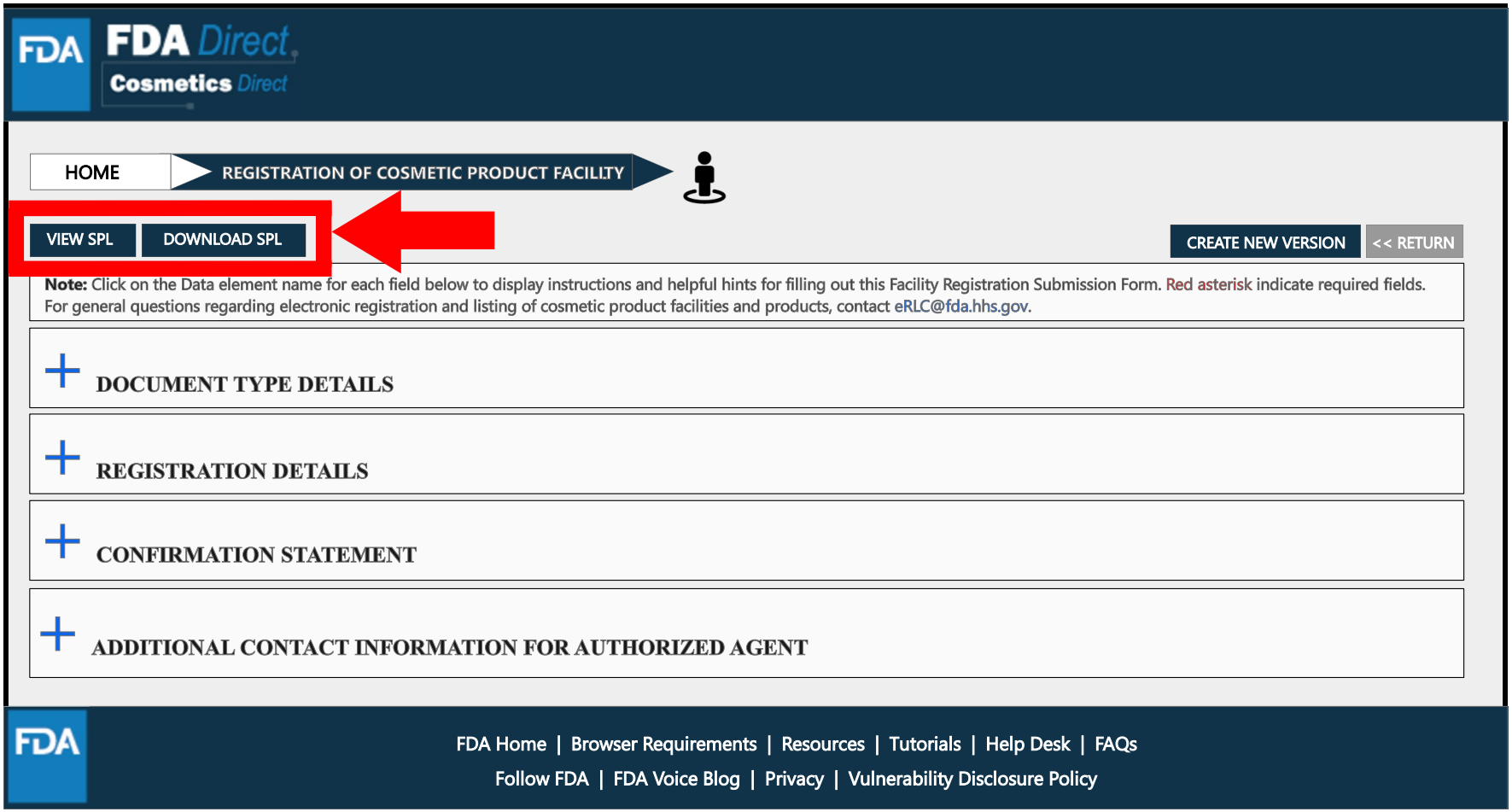
Registration Status: Submit SPL to Submission Accepted

The status will change to **SUBMISSION ACCEPTED** after registration process had been successfully completed. A **SUBMISSION ID** will be given to all **ACCEPTED SUBMISSIONS**.



Registration Status: Submission Accepted to View SPL and Download SPL

By clicking on the **SUBMISSION ACCEPTED** the system will allow the user to **VIEW SPL** and **DOWNLOAD SPL**.

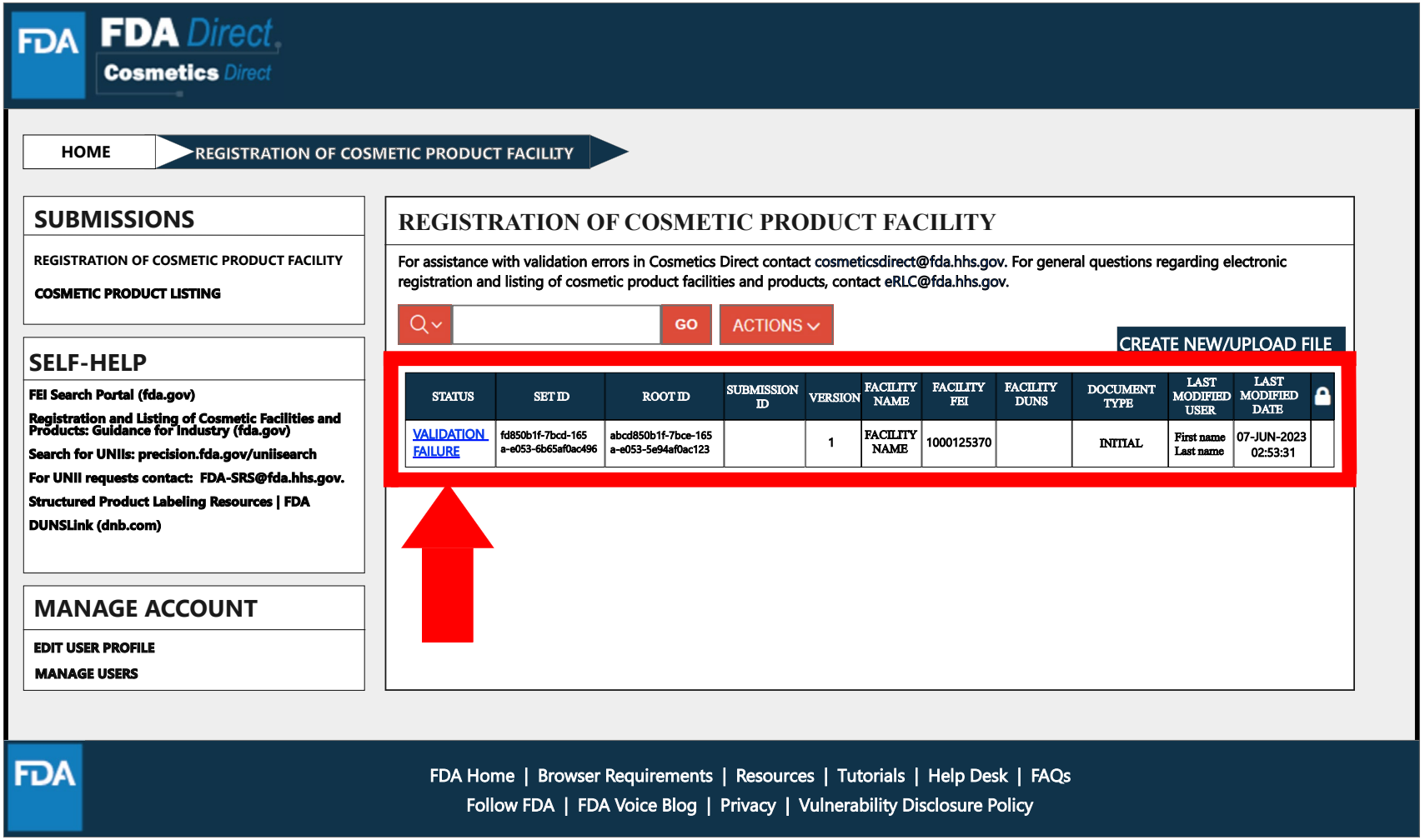


Clone Successfully Submitted SPL

By clicking on the **CREATE A NEW VERSION**, you can clone a successfully-submitted SPL as a starting point.

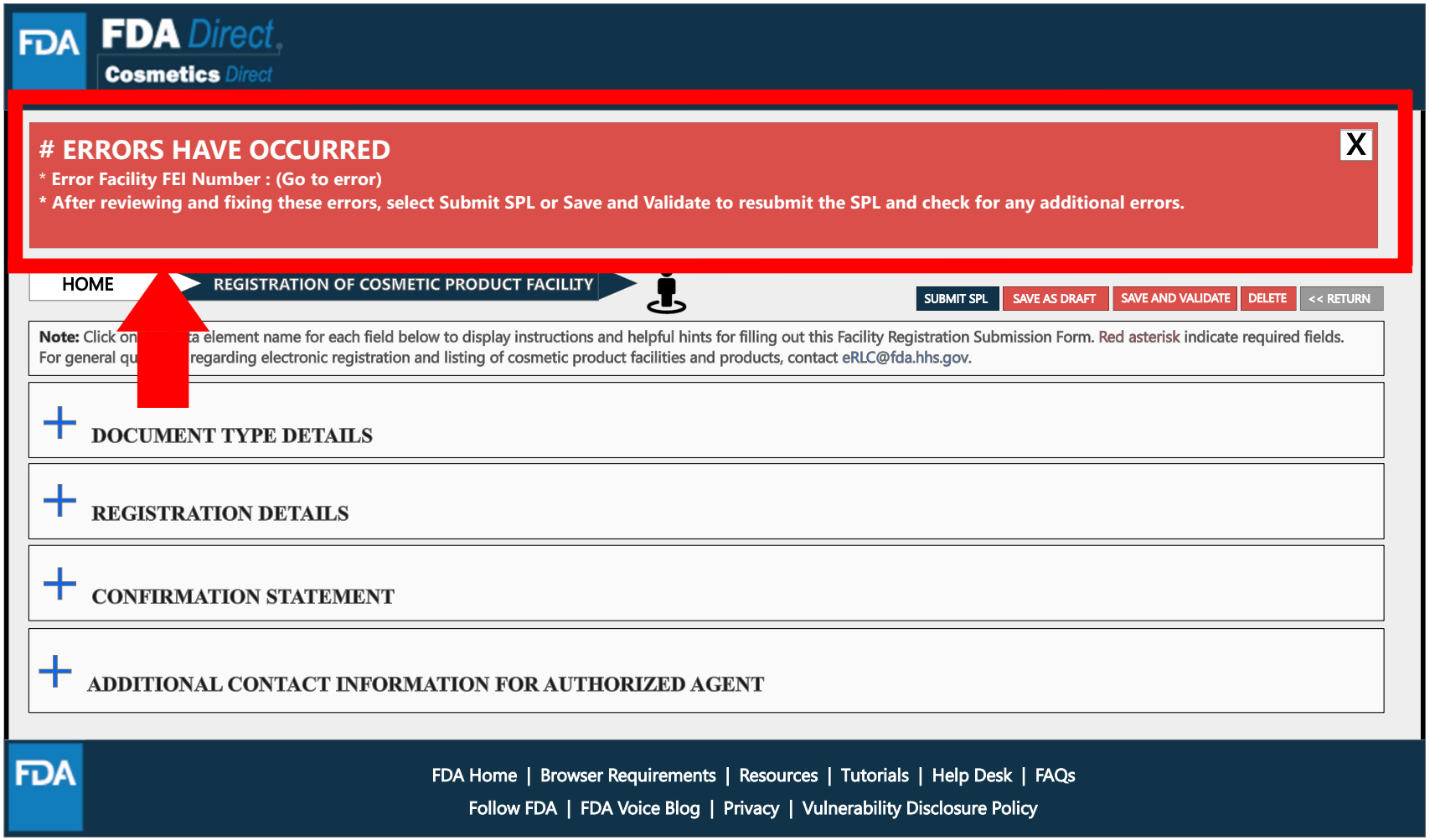
Registration Status: Validation Failure

After SAVE AND VALIDATE, the registration of cosmetic product facility home page will have the following details as shown below. The status will be in **VALIDATION IN PROGRESS**. However, if the system finds any errors the status will change to **VALIDATION FAILURE**.



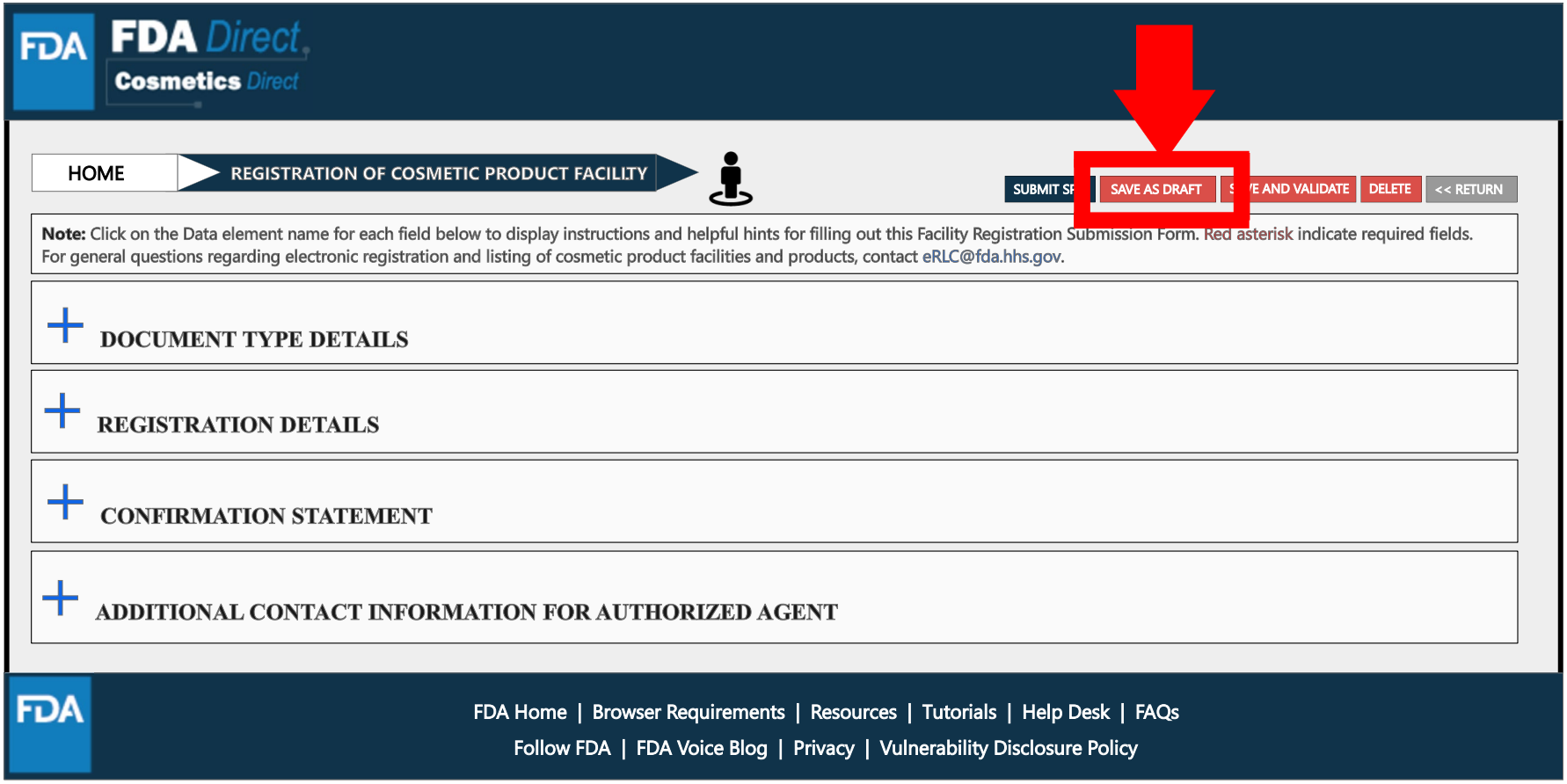
Registration Status: Validation Failure

After selecting the **VALIDATION FAILURE** status, the system will provide a list of errors, that need to be fixed before submitting the SPL. After reviewing and fixing the errors, users can select **SUBMIT SPL** to resubmit the SPL or **SAVE AND VALIDATE** to check for any additional errors.



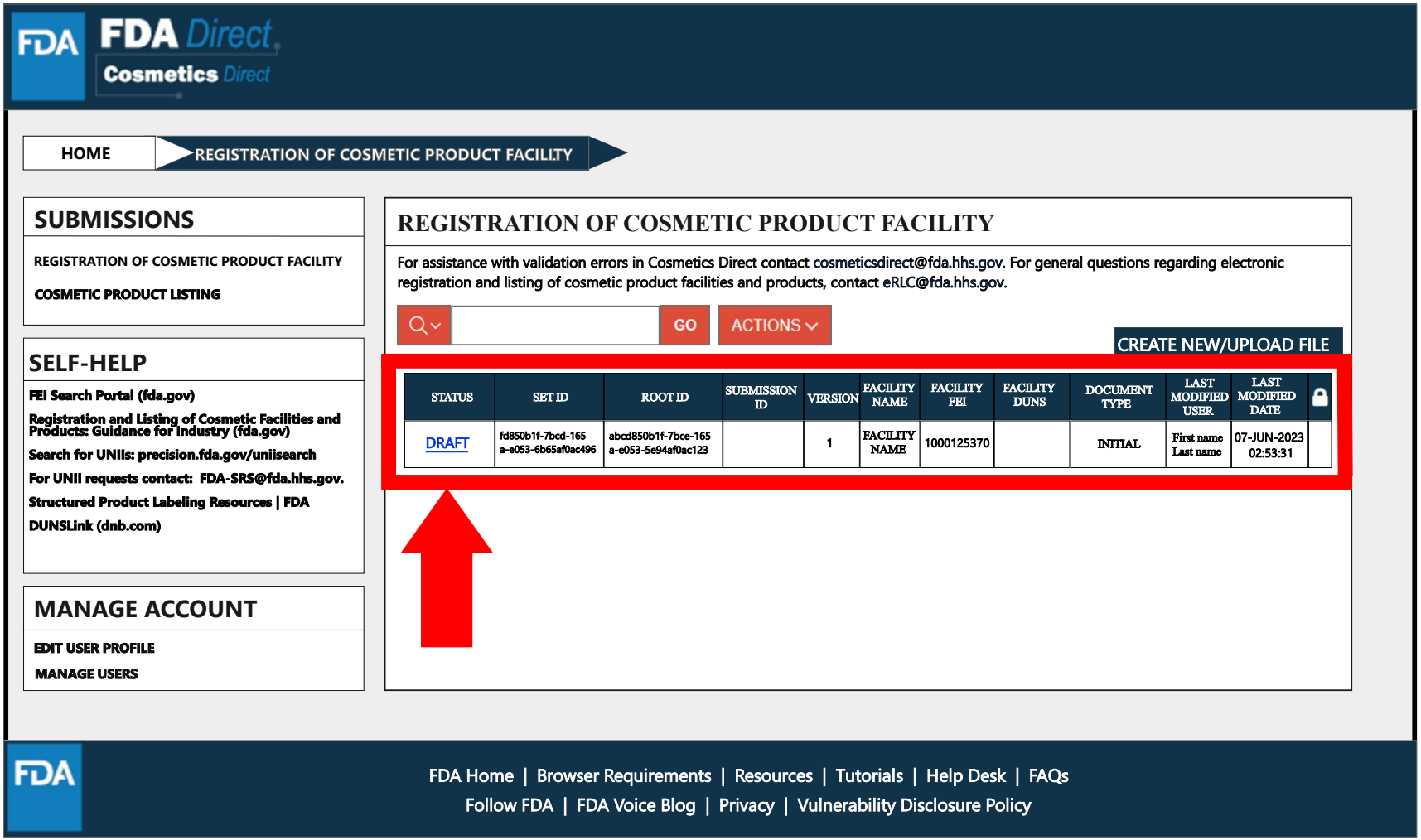
Registration Status: Draft

By selecting **SAVE AS DRAFT**, from any screen during the process of registration of cosmetic product facility, the system saves all information and will bring the user back to the home page. The status will be in **DRAFT**.



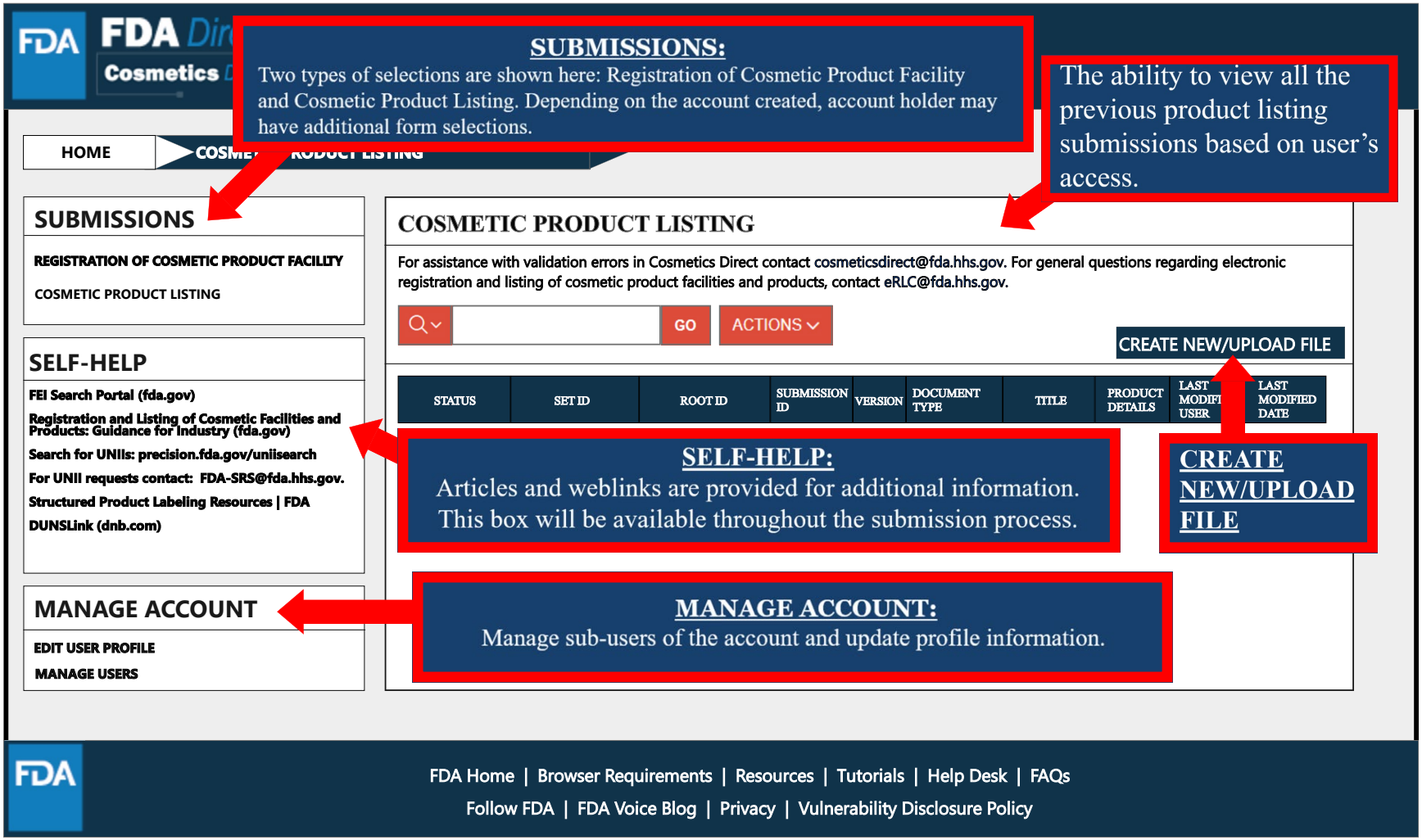
Registration Status: Draft

The registration of cosmetic product facility home page will have the following details as shown below. The status will be in **DRAFT**.



Cosmetic Product Listing

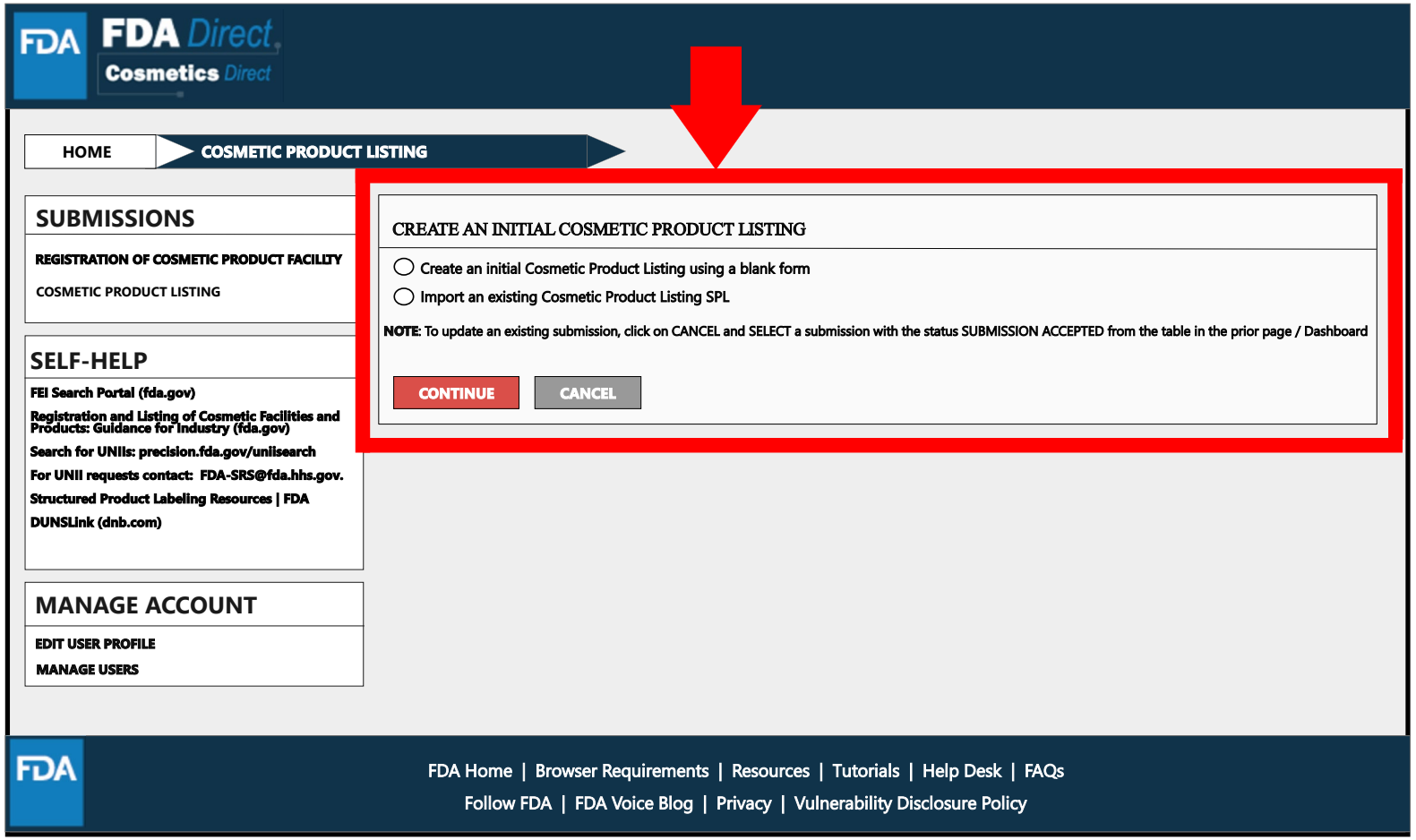
Cosmetic Product Listing Home Page



Create a New Product Listing or Upload an Existing File

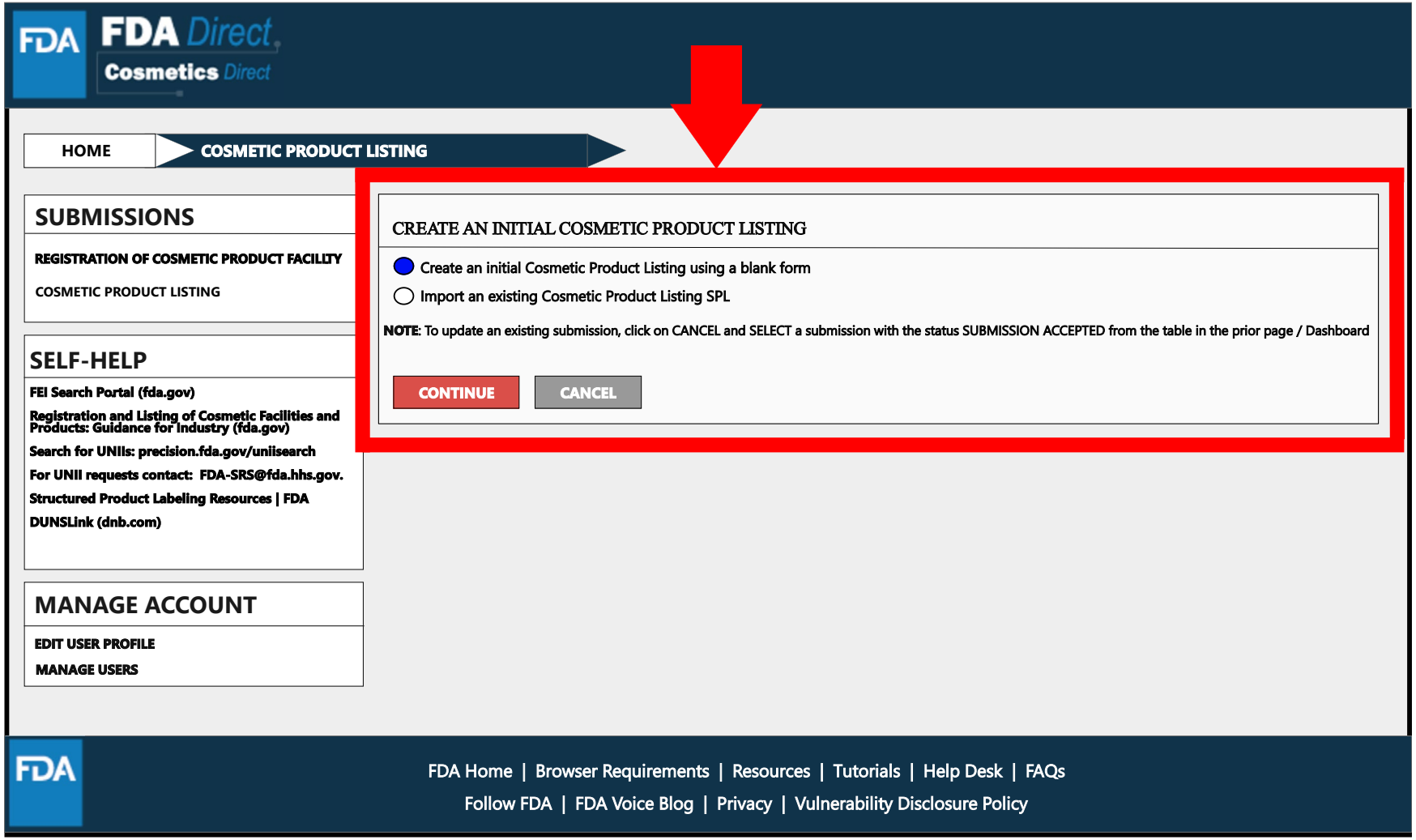
Create a New Product Listing or Upload an Existing File

Selecting the **CREATE NEW/UPLOAD FILE** box, from the **Cosmetic Product listing home page** will direct user to this page with an option of creating an initial Cosmetic Product Listing using a blank form or import an FDA-accepted SPL stored on your computer in a valid XML zip file. SPL (Structured Product Labeling) is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product and facility information. Importing an existing Cosmetic Product Listing SPL will be beneficial for bulk submission.

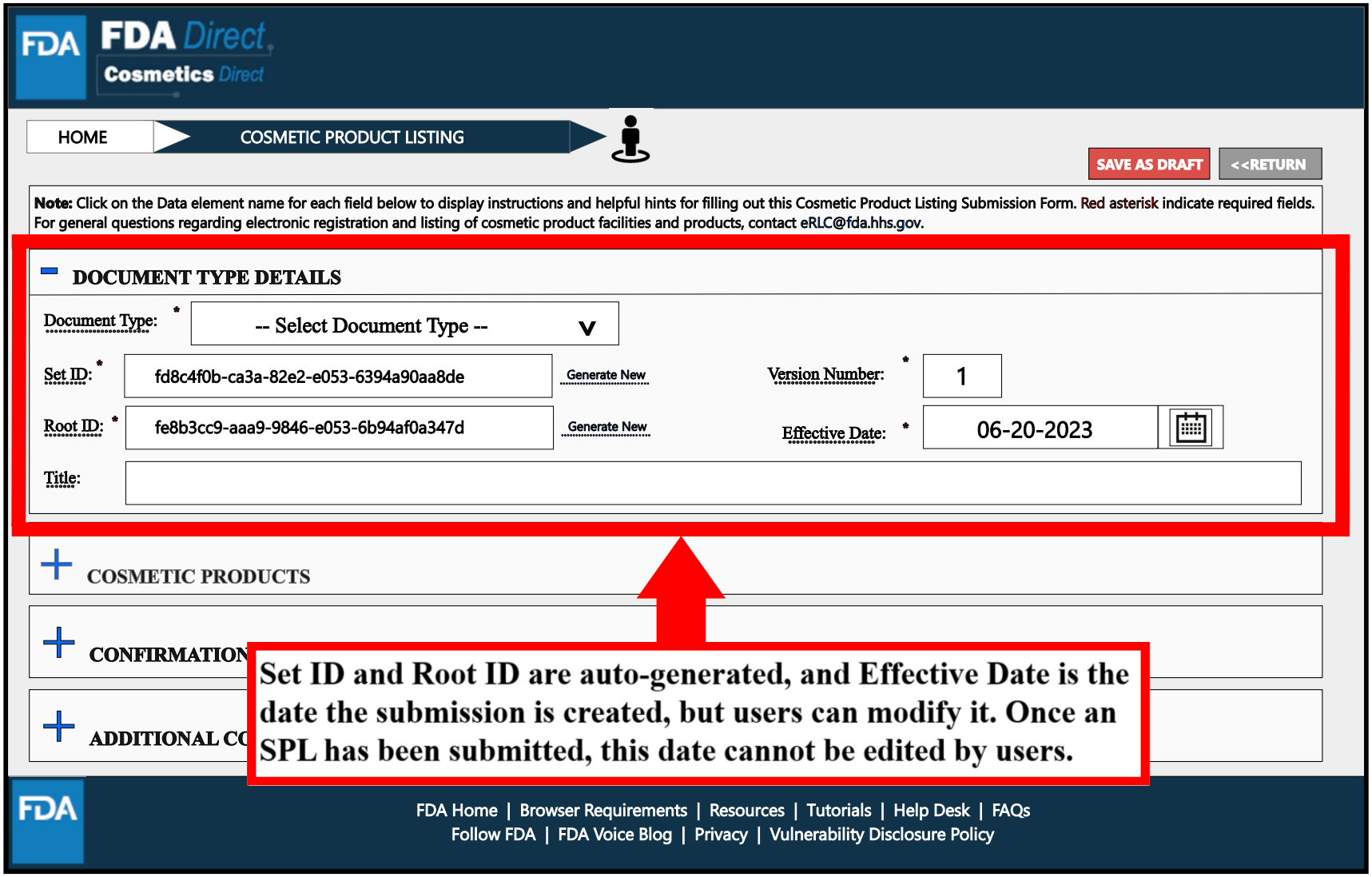


Create a New Cosmetics Product Listing

Create an Initial Cosmetic Product Listing using a blank form.

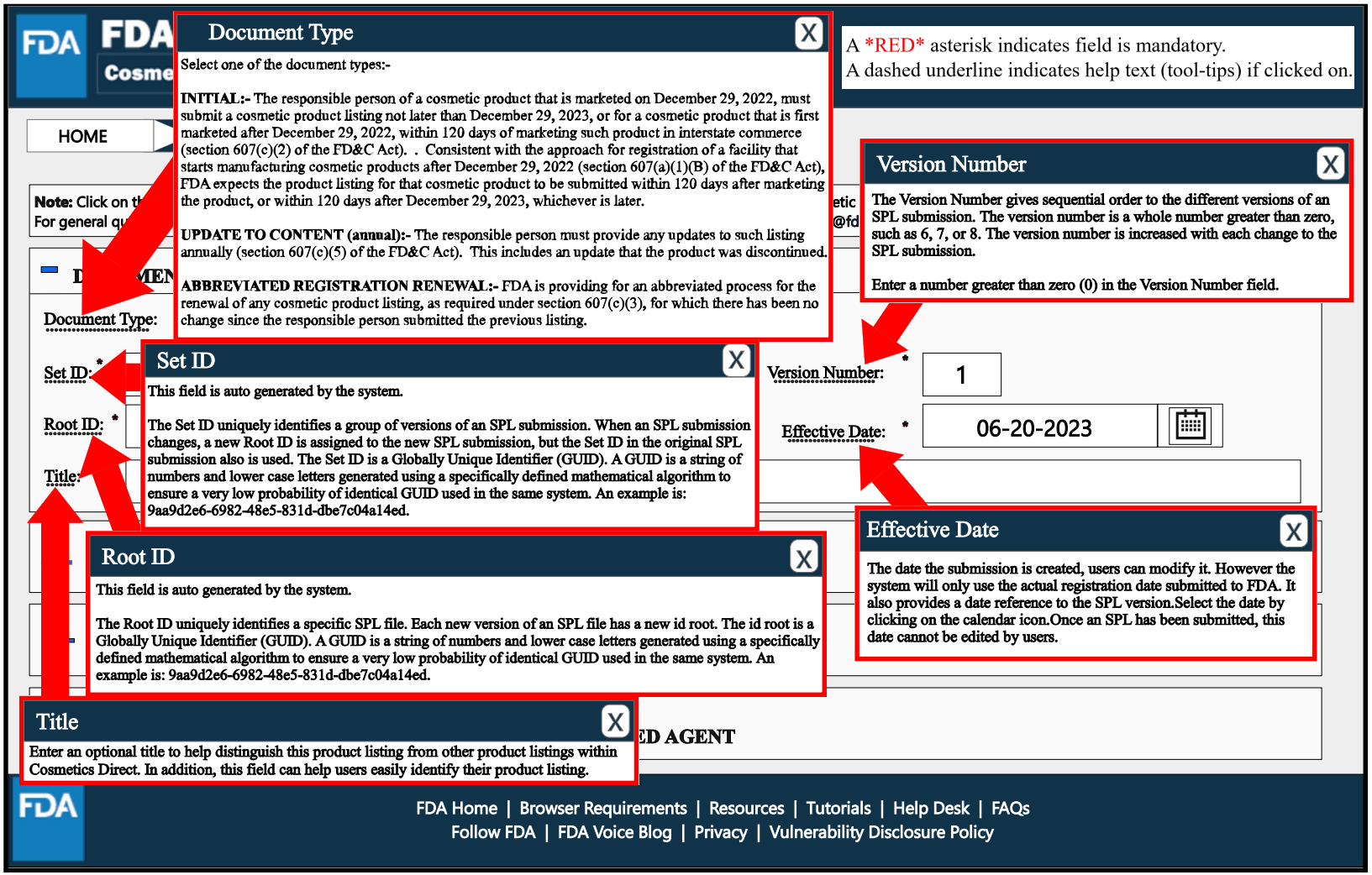


Document Type Details



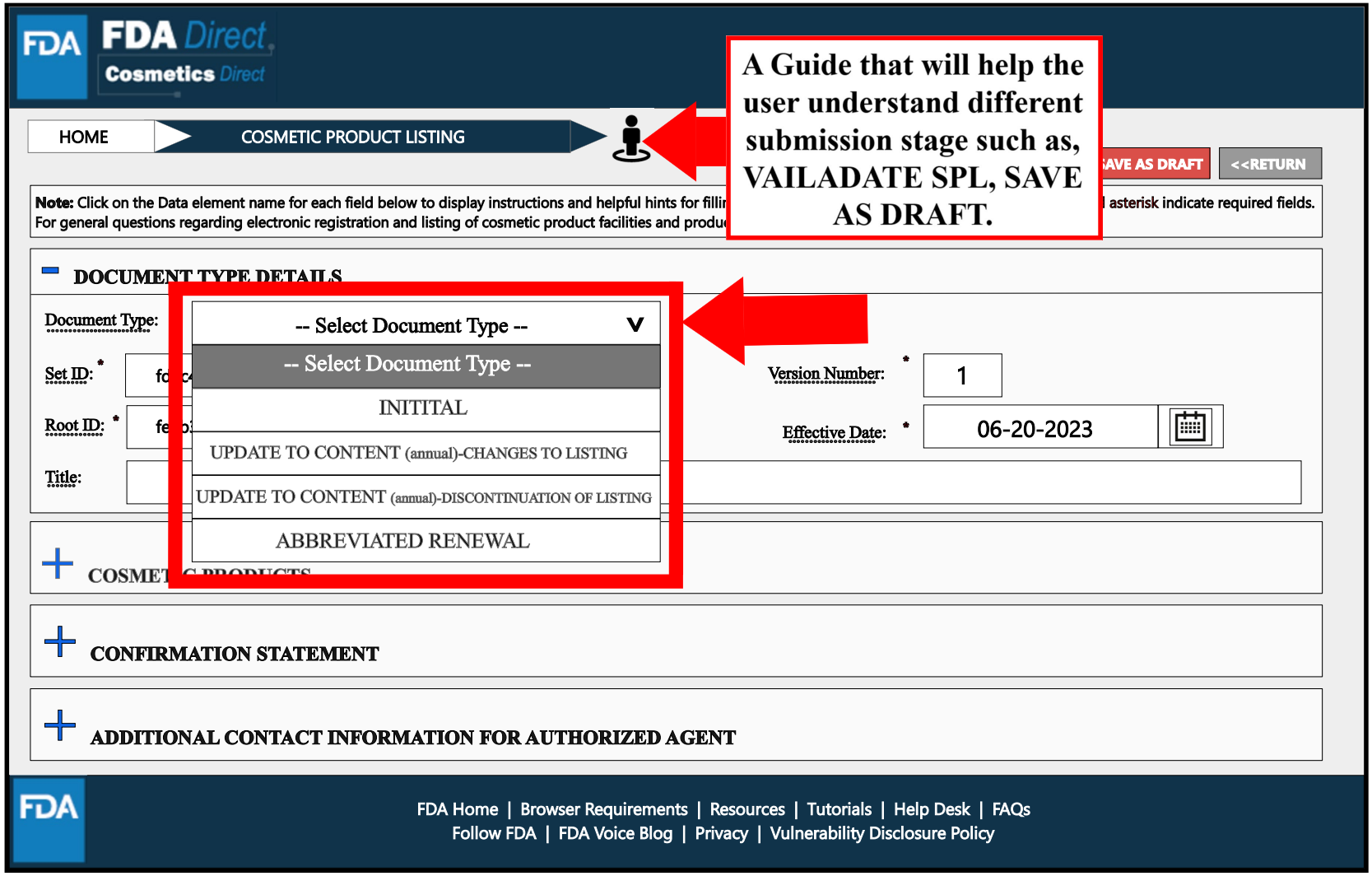
Document Type Tool Tips

A *RED* asterisk indicates field is mandatory. Dashed underline indicates help text (tool-tips) if clicked on.



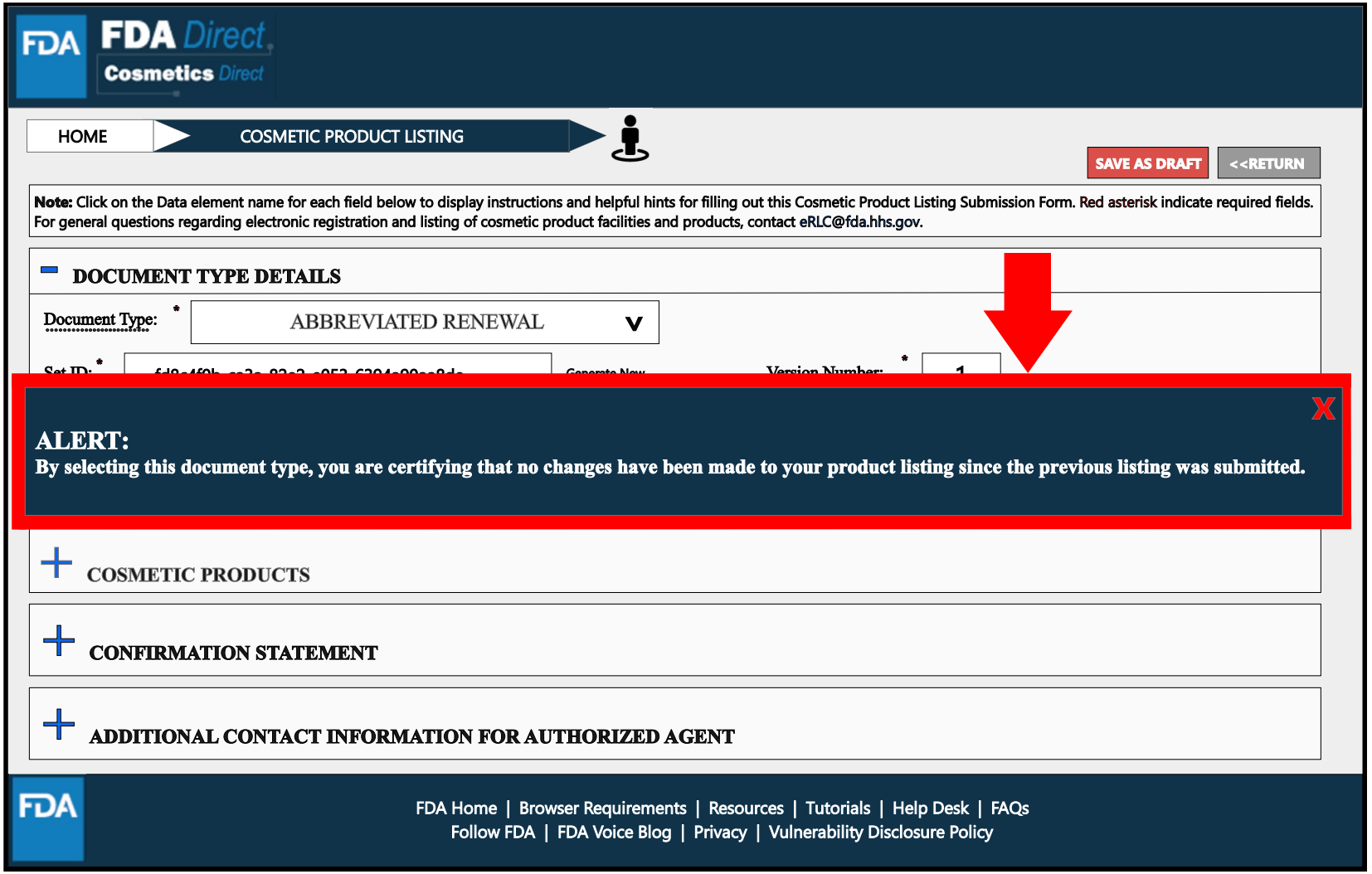
Document Type Details

By selecting the drop-down (v), four document types options will appear; initial, update to content (annual)-changes to listing, update to content (annual)-discontinuation of listing, and abbreviated renewal.

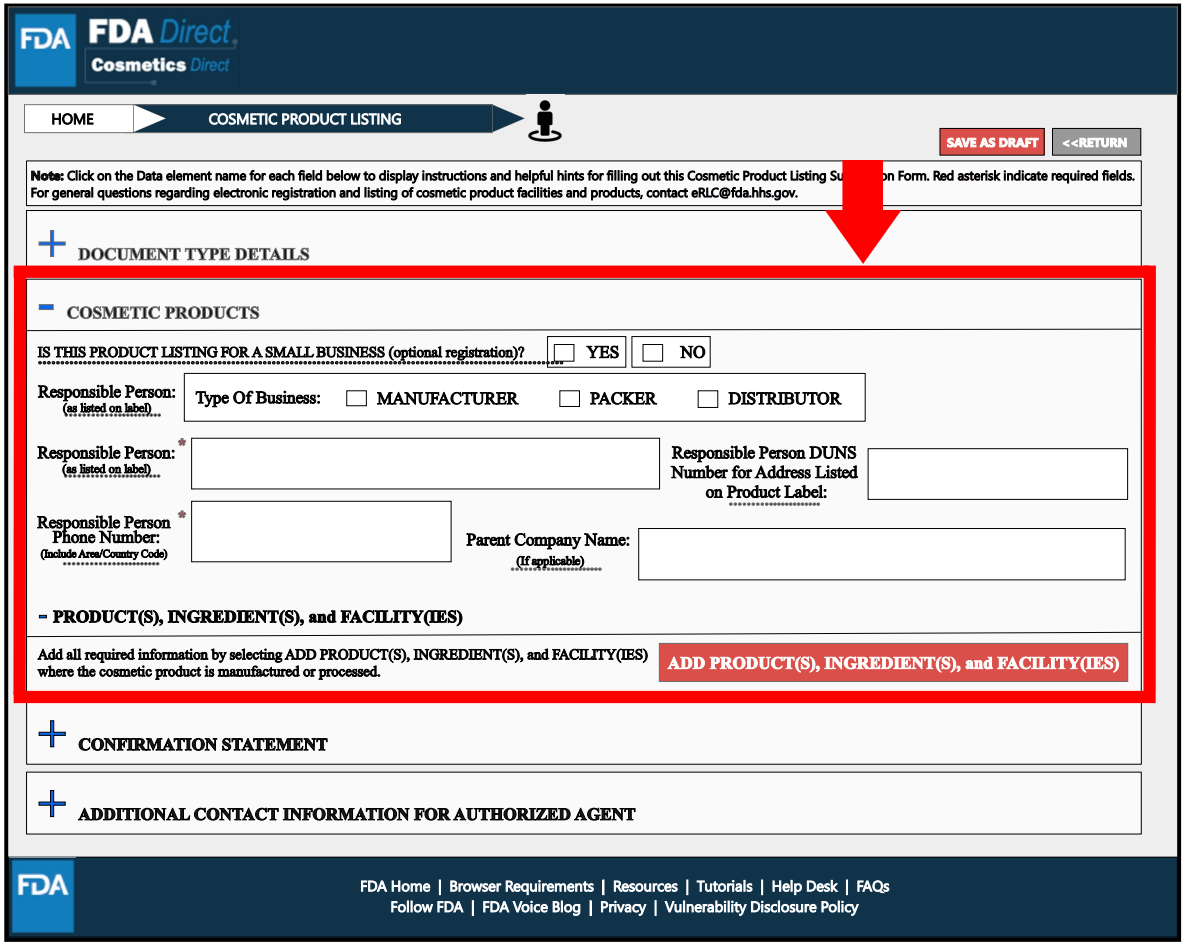


Document Type Details

Depending on which document type is selected, an ALERT box will appear, "*By selecting this document type, you are certifying that no changes have been made to your product listing since the previous listing was submitted*".



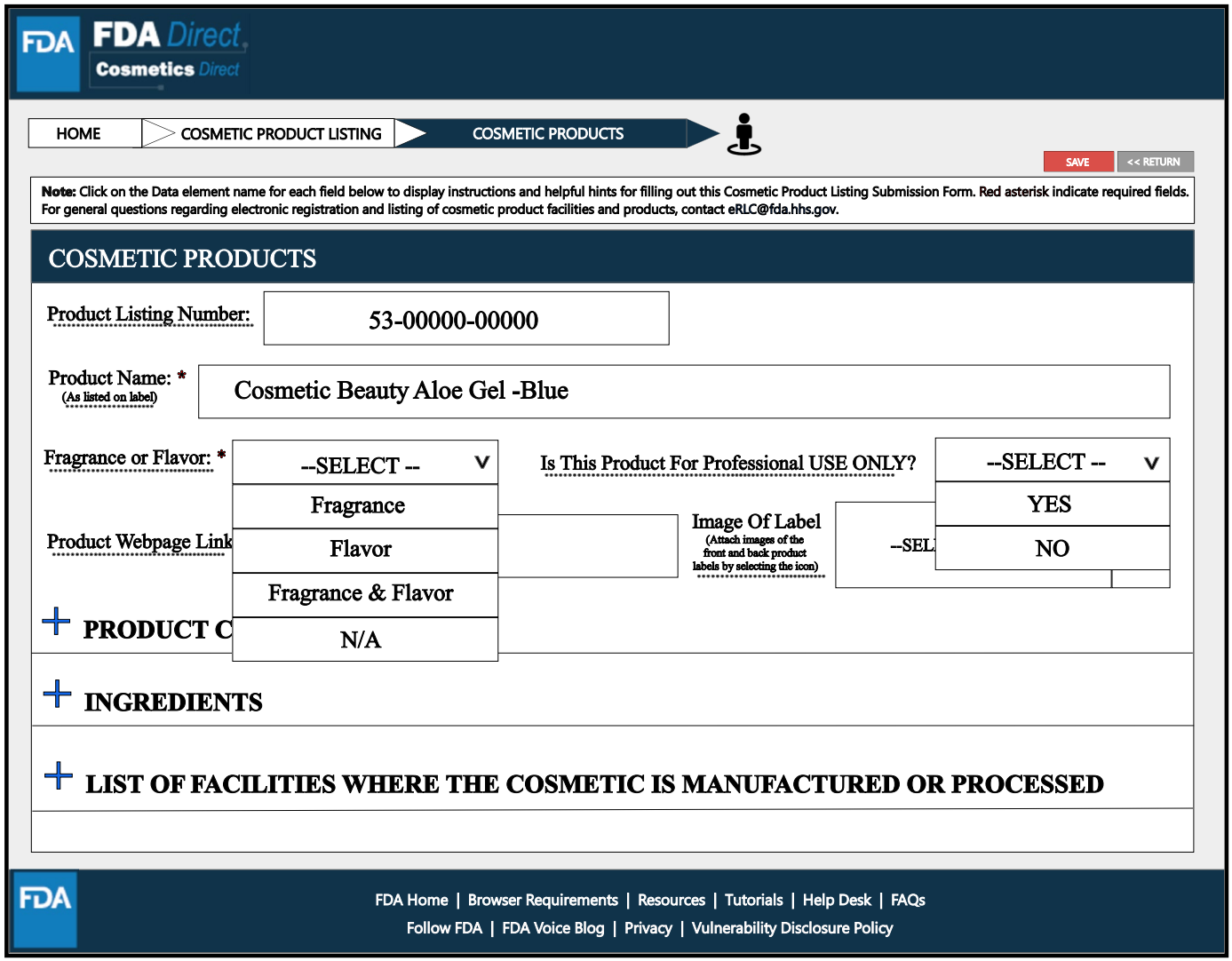
Cosmetic Products



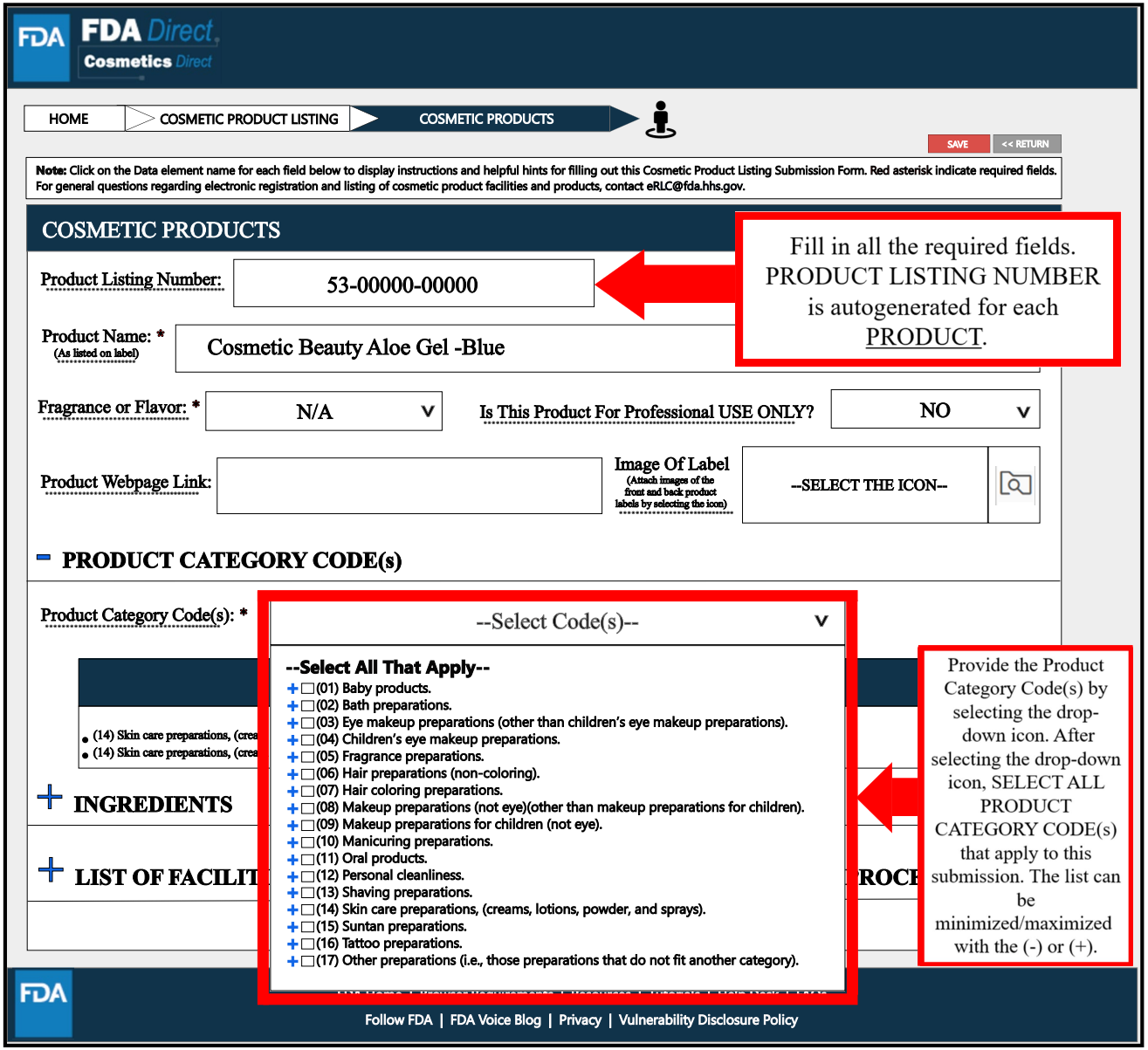
A ***RED*** asterisk indicates field is mandatory. A dashed underline indicates help text (tool-tips). To list all the PRODUCTS, INGREDIENTS and FACILITIES where the cosmetic product is manufactured or processed, select **ADD PRODUCT(S), INGREDIENT(S) and FACILITY(IES)**.

Products, Ingredients, and Facilities

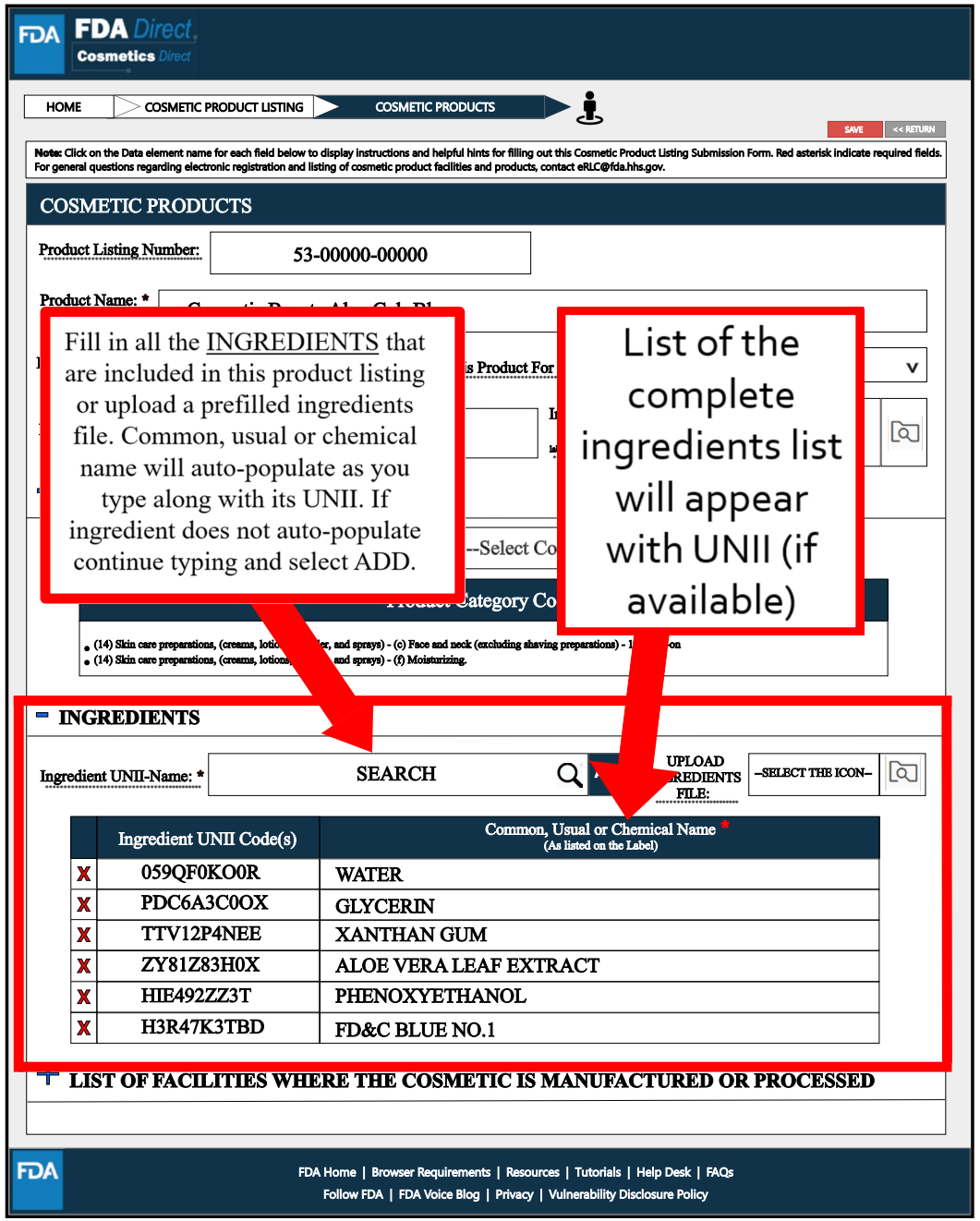
Provide all the information required for PRODUCT(S), INGREDIENT(S) and FACILITY(IES) where the cosmetic product is manufactured or processed.



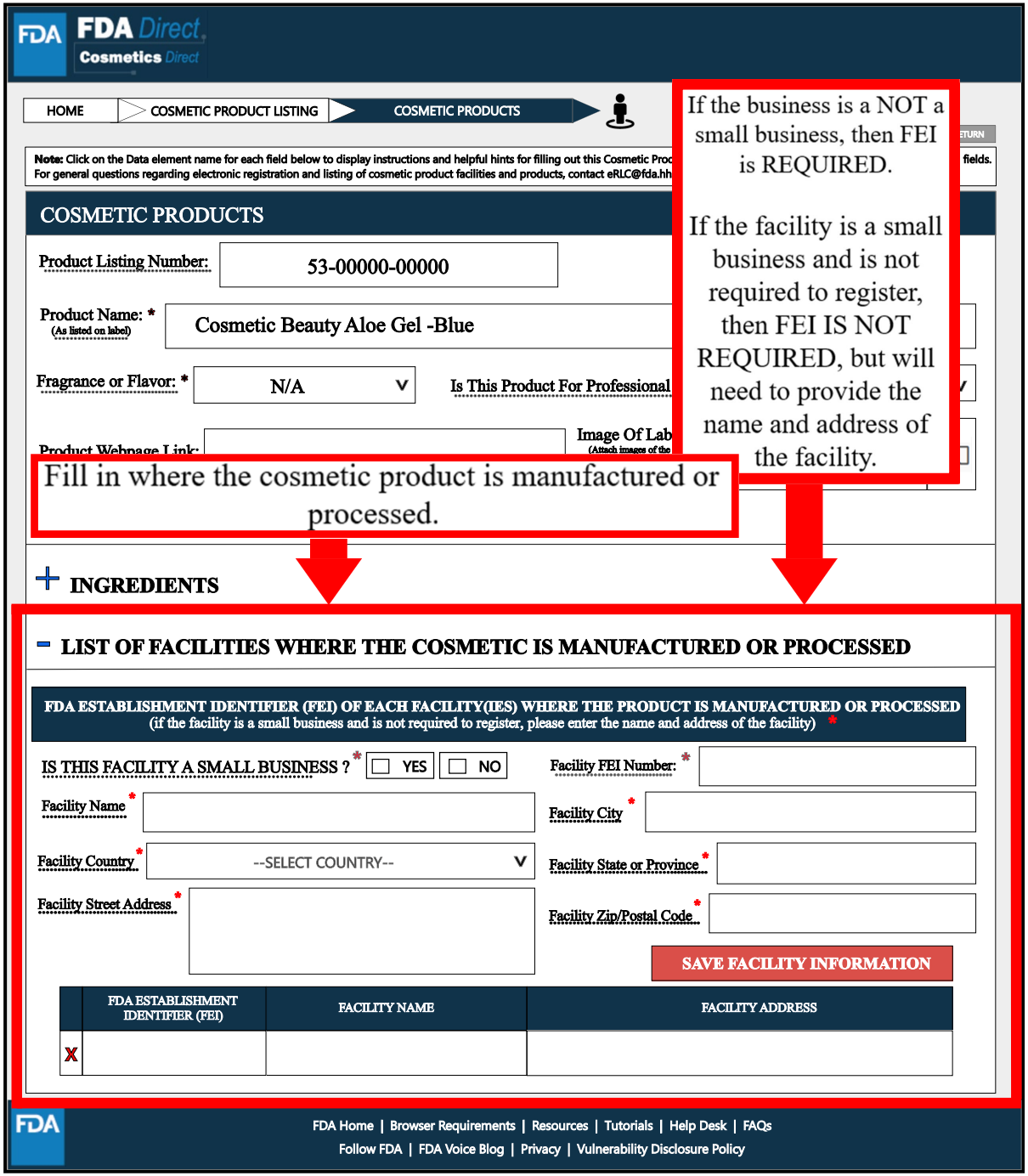
Product Category Code(s) (Example)



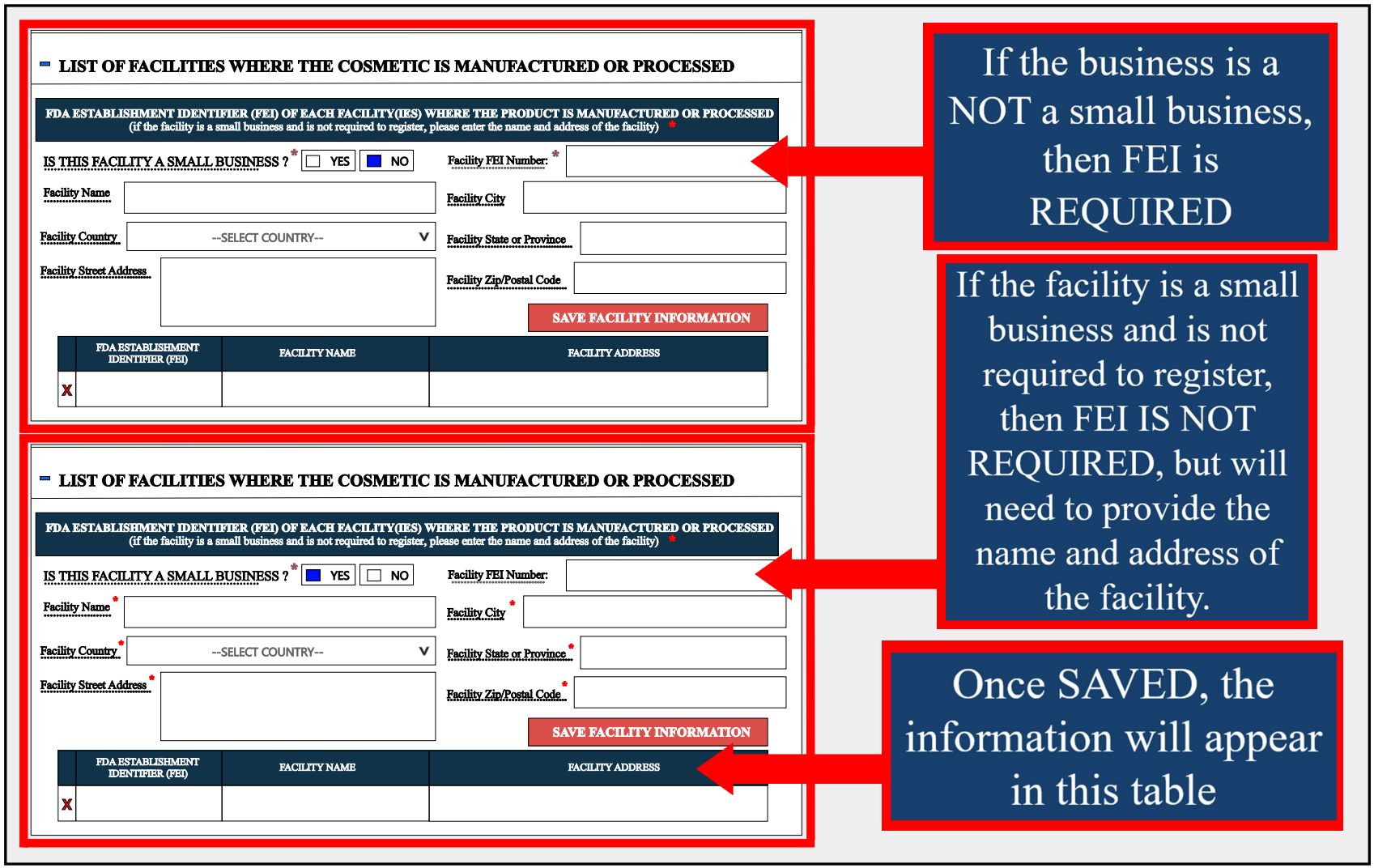
Listing Ingredients (Example)



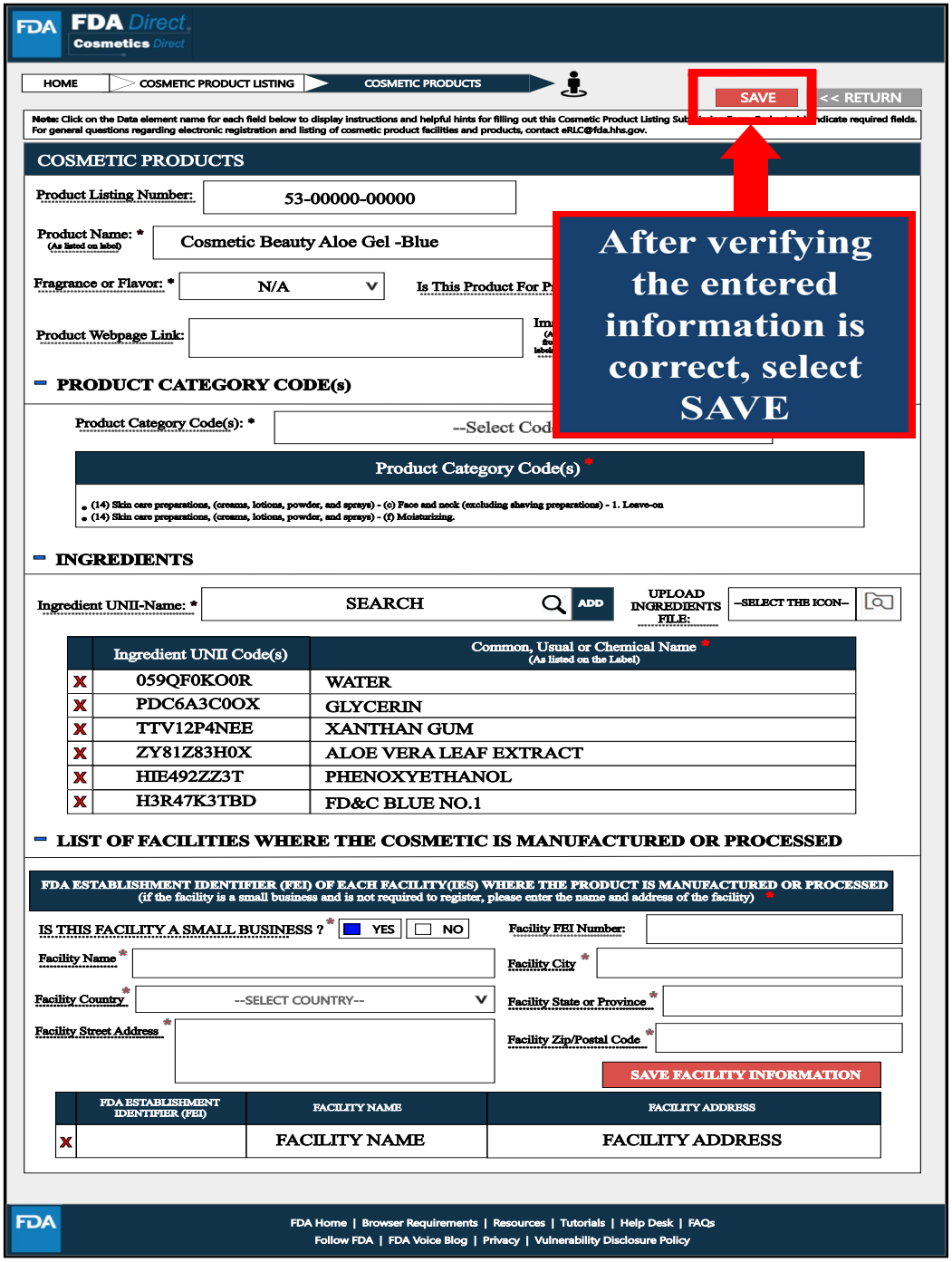
List of Facility(ies) (Example)



List of Facility (Example)

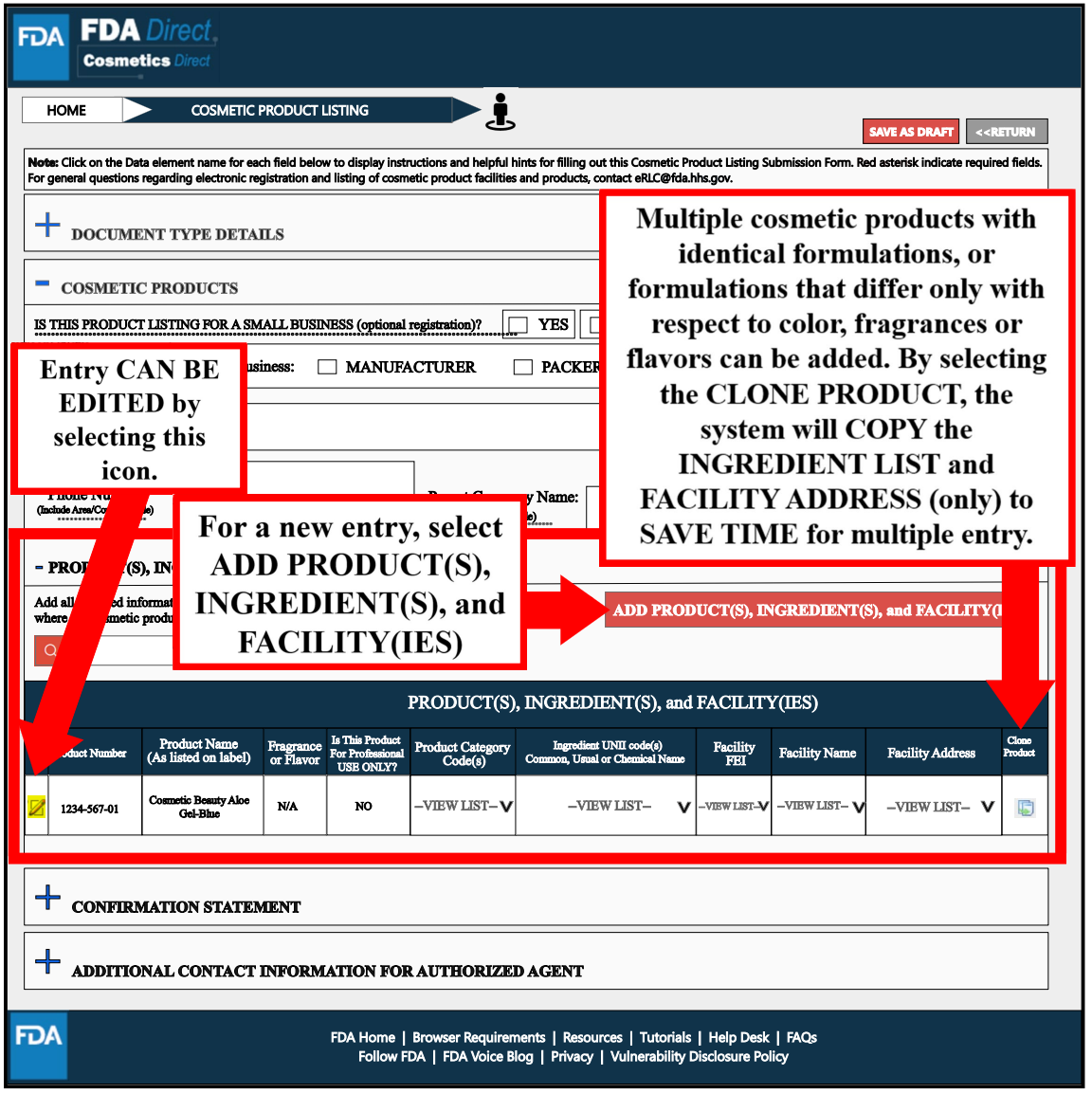


Example of a Complete Listing (Products, Ingredients, and Facilities Tab)

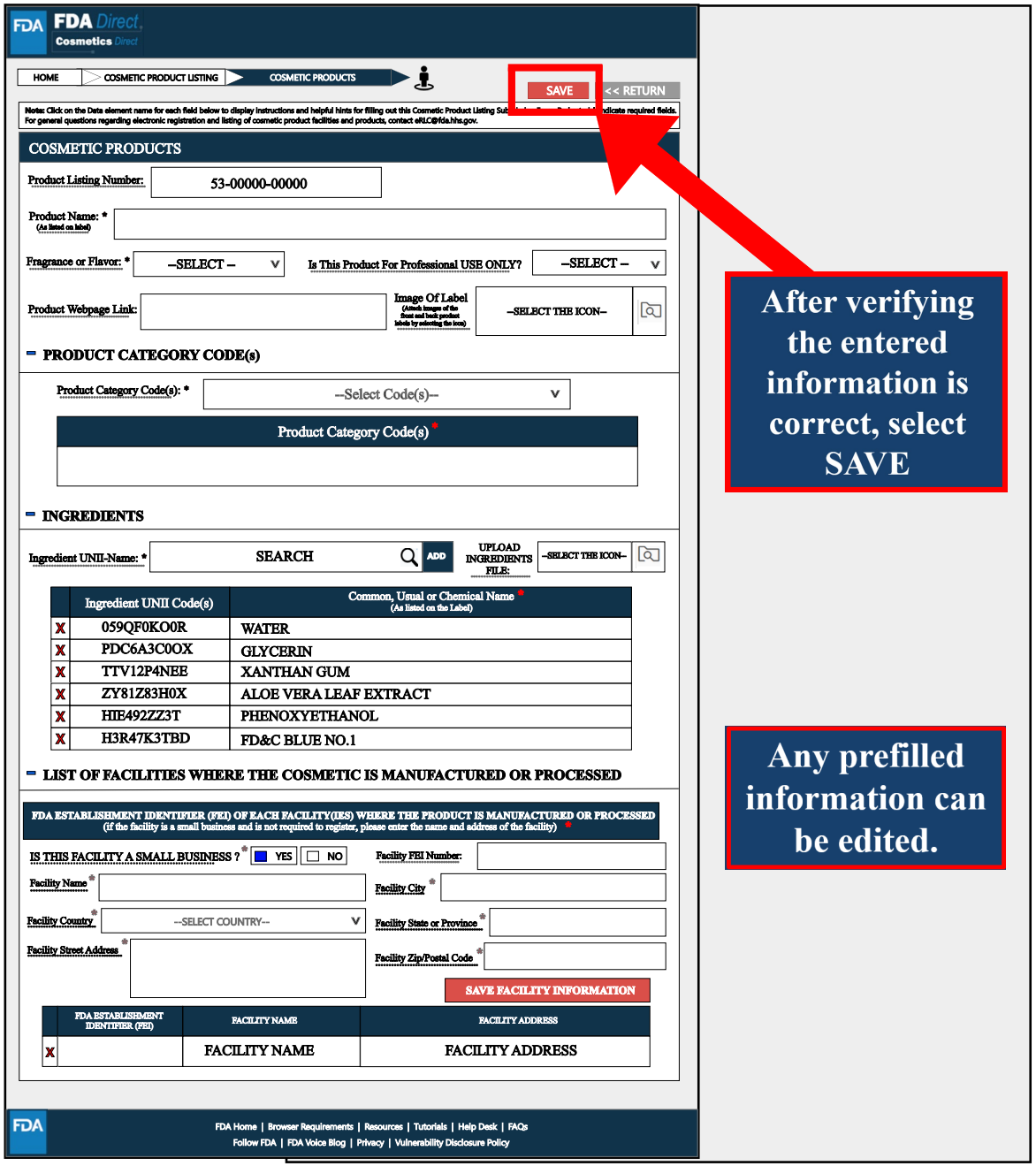


Products, Ingredients, and Facilities

The information that was provided in the pop-up will appear under PRODUCT(S), INGREDIENT(S) and FACILITY(IES).



Example of a Prefilled Clone

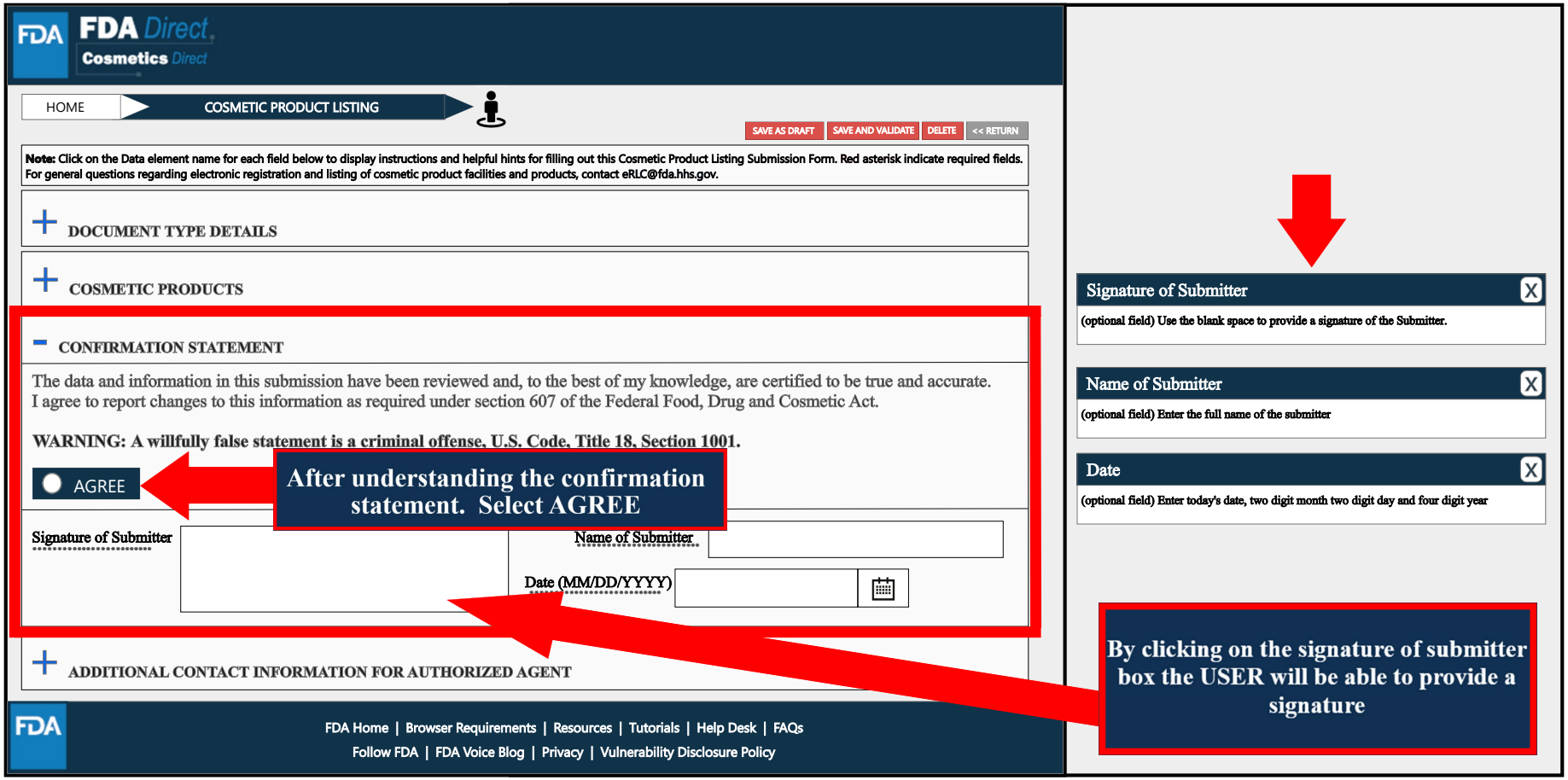


After verifying the entered information is correct, select SAVE

Any prefilled information can be edited.

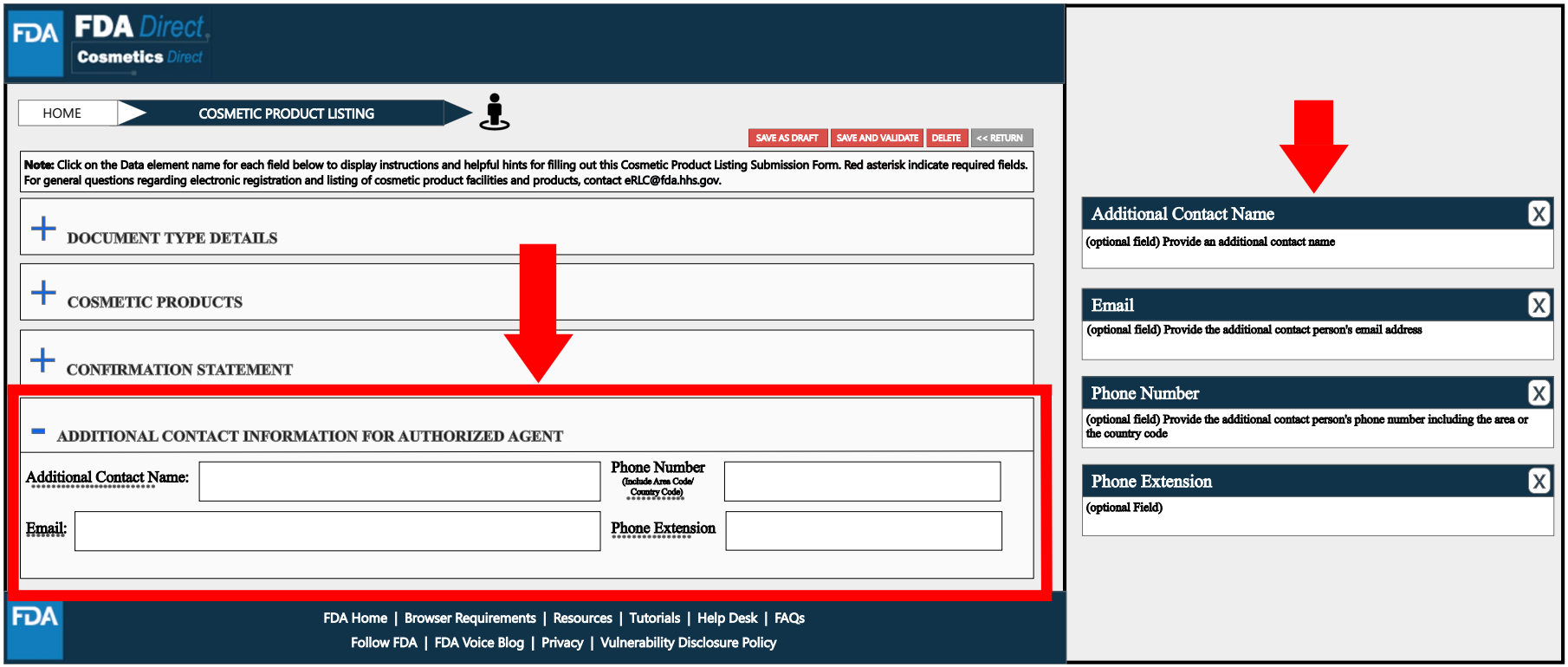
Confirmation Statement

A dashed underline indicates help text (tool-tips) if clicked on, as listed below.



Additional Contact Information for Authorized Agent

A dashed underline indicates help text (tool-tips) if clicked on, as listed below.

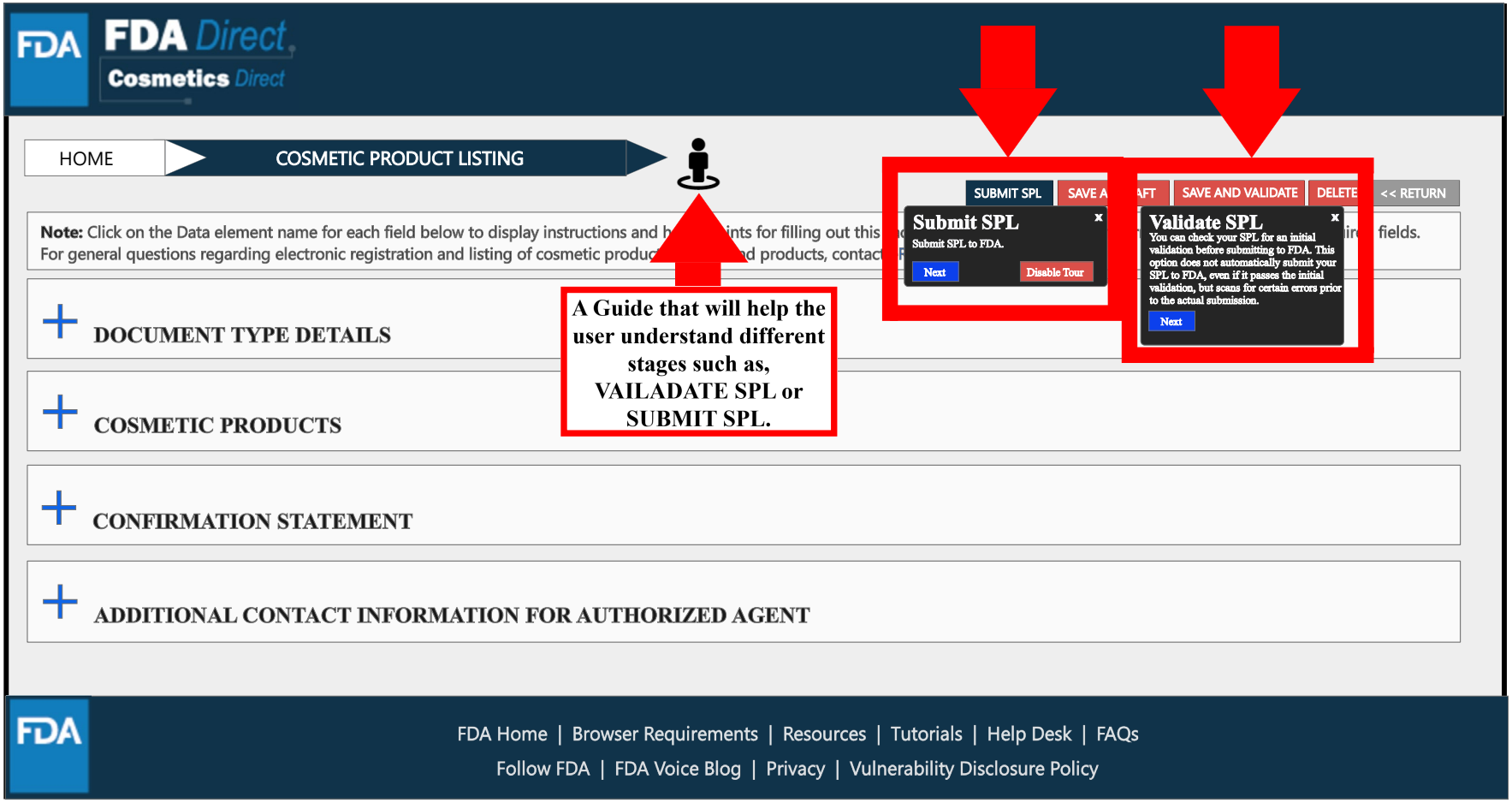


Completed

After filling in all the required information, **SAVE AND VALIDATE**, to identify any errors.

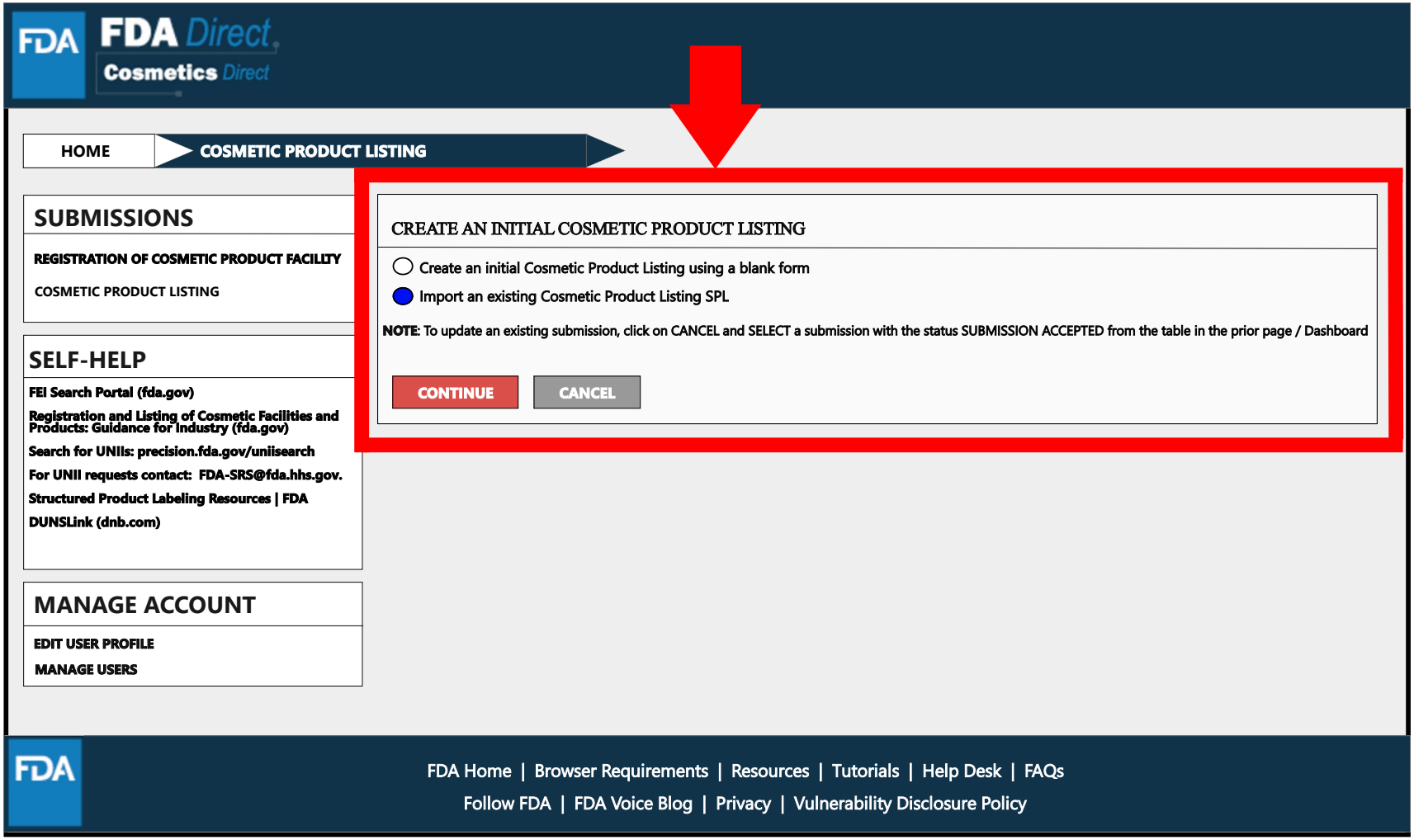
OR

Select **SUBMIT SPL** for the form to be submitted to FDA.



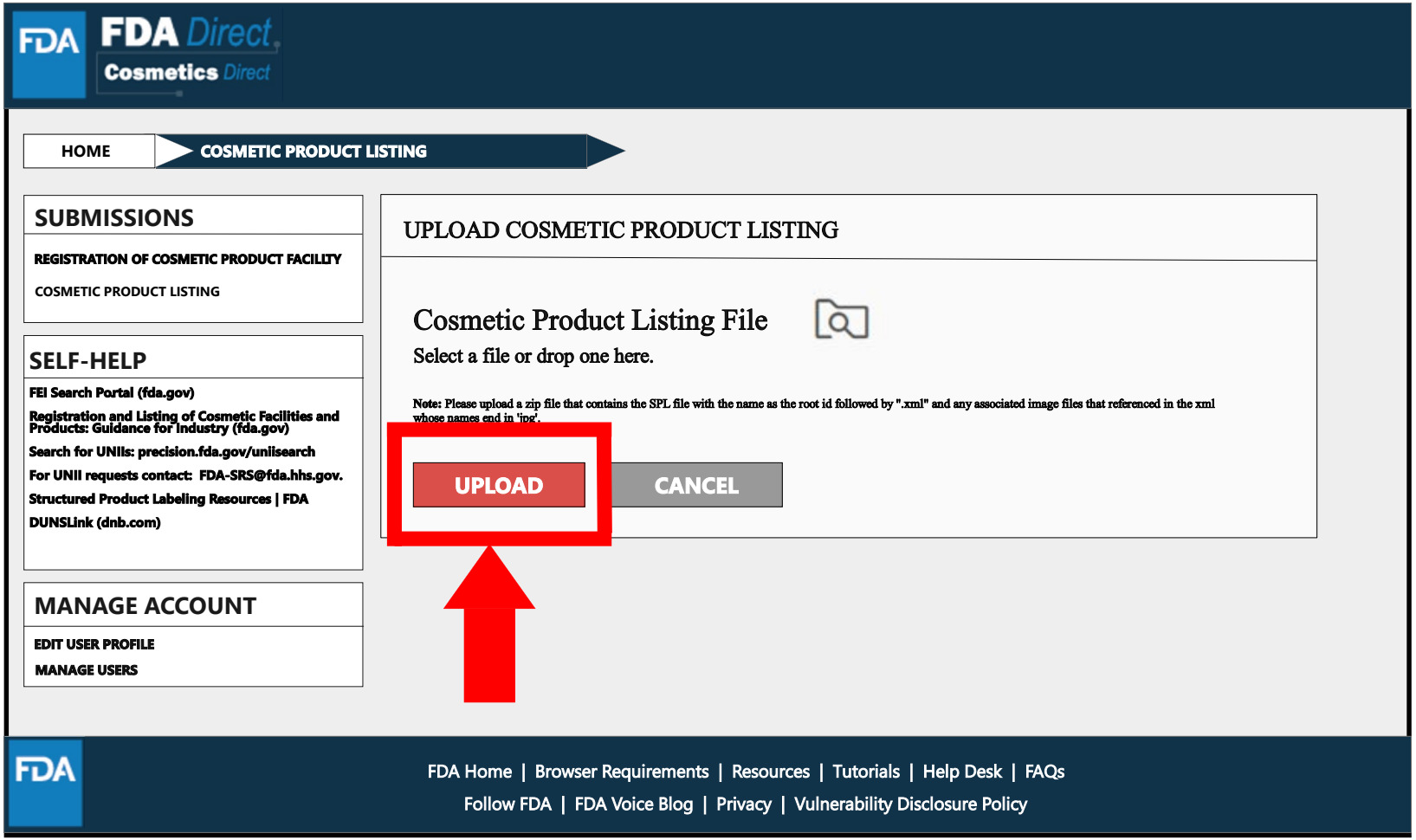
Upload a File

In order to upload a file, select **Import an existing Cosmetic Product Listing SPL**. Importing an existing Cosmetic Product Listing SPL will be beneficial for bulk submission.



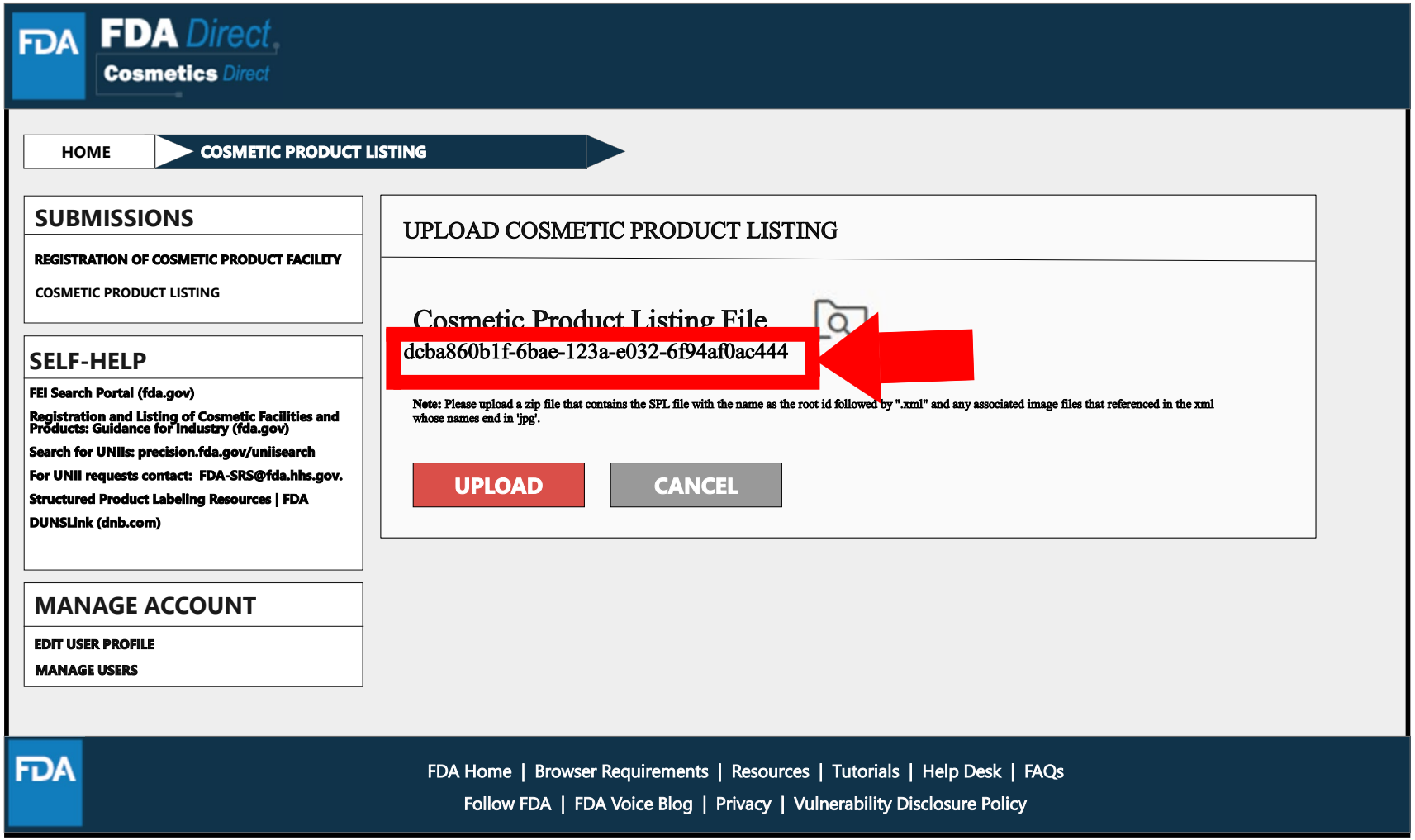
Upload a File

User will be able to upload a pre-existing ZIP FILE, this file may contain both the xml file and image (jpg) files. SPL(Structured Product Labeling) is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product and facility information. For more information regarding SPL, utilize the **Structured Product Labeling Resources** (SPL) link provided under **SELF-HELP**.



Upload a File (example)

The content in the red circle is an example to what a zip file could be, may contain .xml file and image (jpg) files.



Zip File (example)

An example to what an XML format could look like.

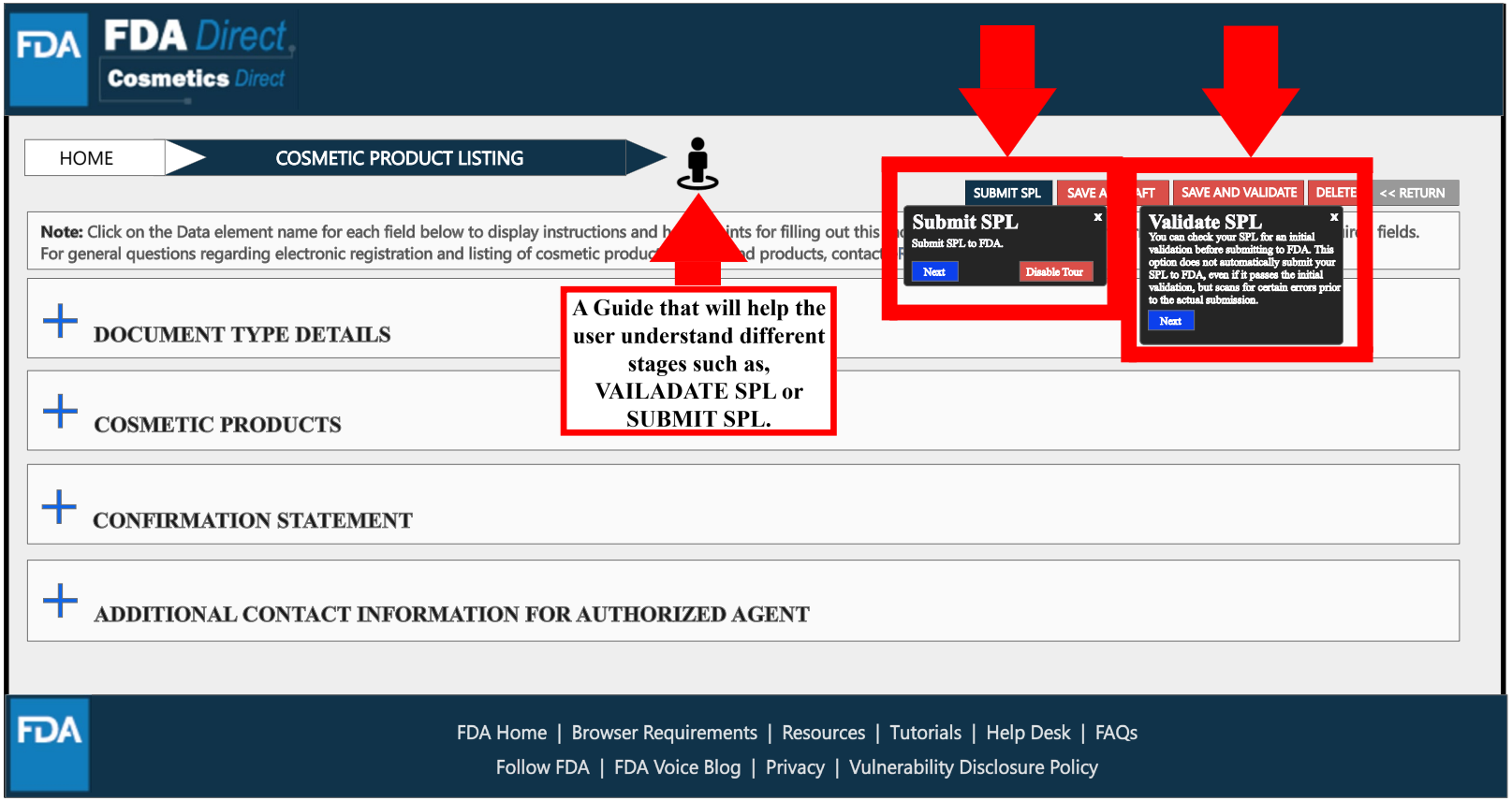
```
<?xml version="1.0" encoding="UTF-8"?>
<?xml-stylesheet href="https://www.accessdata.fda.gov/spl/stylesheet/spl.xsl" type="text/xsl"?>
<document xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:schemaLocation="urn:hl7-org:v3 https://www.accessdata.fda.gov/spl/schema/spl.xsd">
  <id root="fd8c4f0b-ca3b-82e2-e053-6394a90aa8de"/>
  <code code="51725-0" codeSystem="2.16.840.1.113883.6.1" displayName=" COSMETIC PRODUCT
LISTING "/>
  <effectiveTime value="[DATE]"/>
  <setId root="fd8c4f0b-ca3a-82e2-e053-6394a90aa8de"/>
  <versionNumber value="1"/>
  <author>
   <time/>
   <assignedEntity>
    <representedOrganization>
     <assignedEntity>
      <assignedOrganization>
       <id root="1.3.6.1.4.1.519.1" extension="314988747"/>
```

Upload a File (Example)

After **UPLOADING A FILE** (XML ZIP FILE), the system will auto-fill all the required fields and the form will be ready to save and validate to check for any errors. This is an easy way to submit multiple Cosmetic Product Listing under one submission ID.

VALIDATE SPL: *"You can check your SPL for an initial validation before submitting to FDA. This option does not automatically submit your SPL to FDA, even if it passes the initial validation, but scans for certain errors prior to the actual submission."*

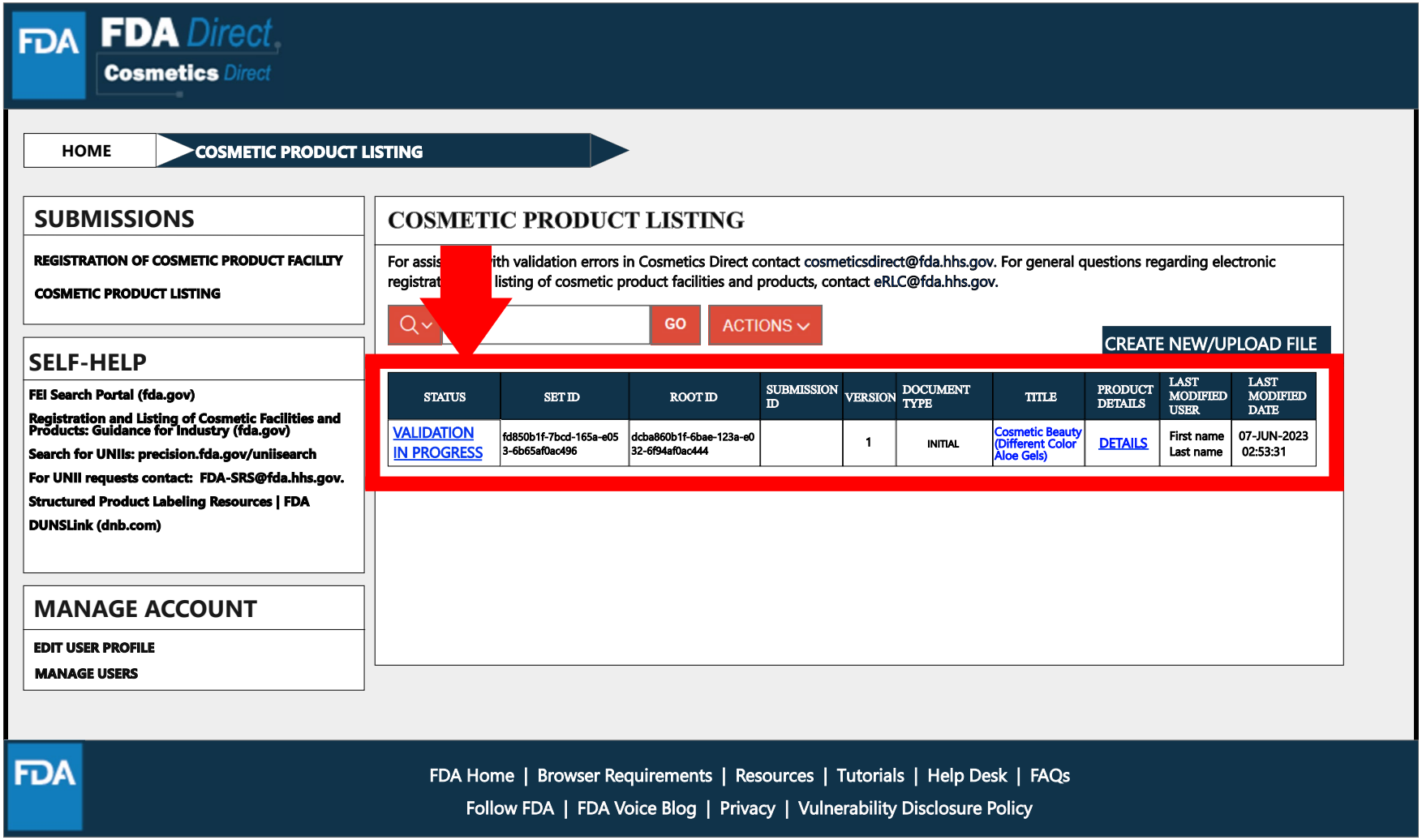
Select **SUBMIT SPL** for the form to be submitted to FDA. The Submit SPL box is a help tool that can guide a user through the process.



Product Listing Status Examples

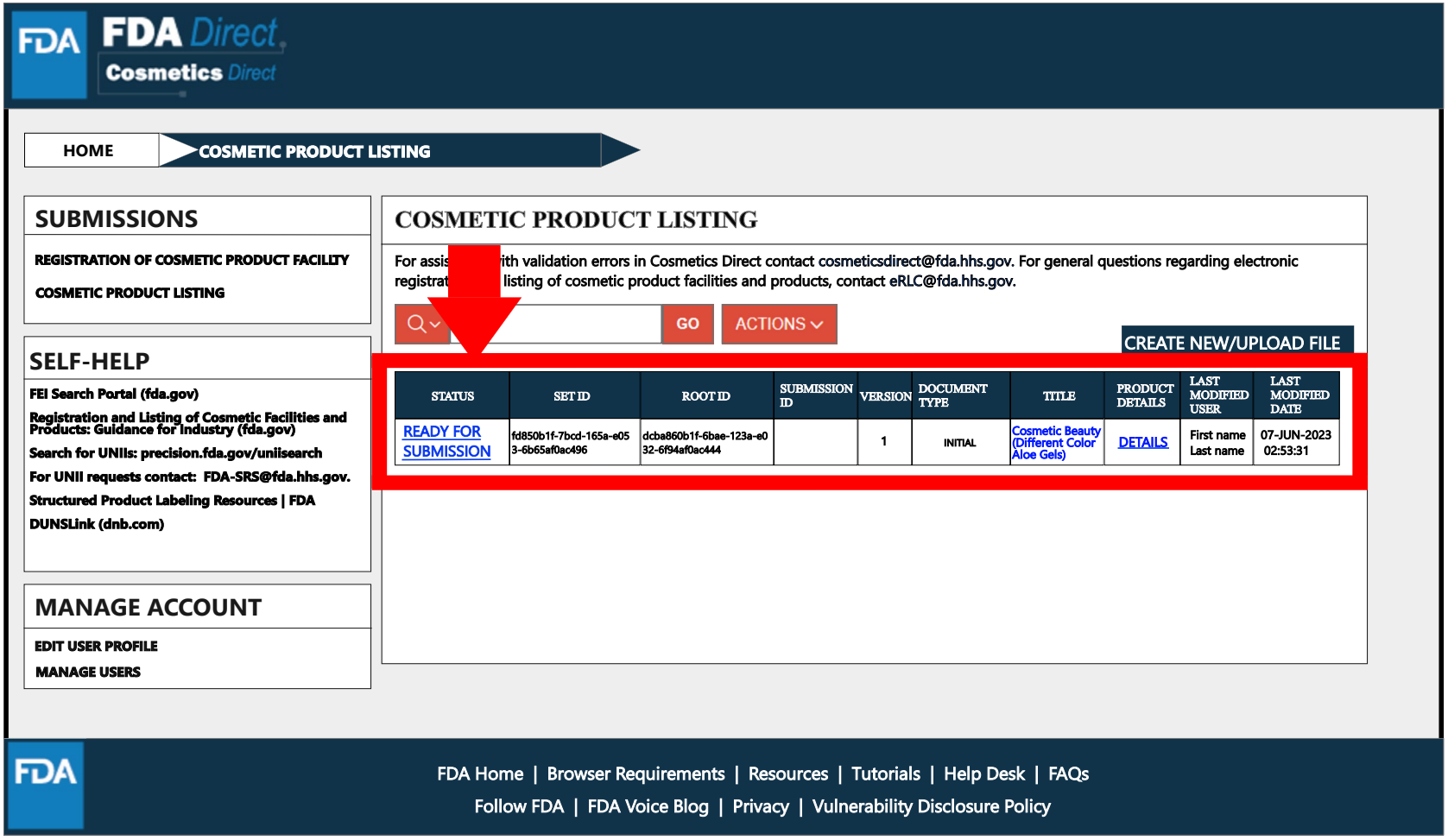
Listing Status: Validation in Progress

After SAVE AND VALIDATE, the cosmetic product Listing home page will have the following details as shown below. The status will be in **VALIDATION IN PROGRESS**.



Listing Status: Ready for Submission

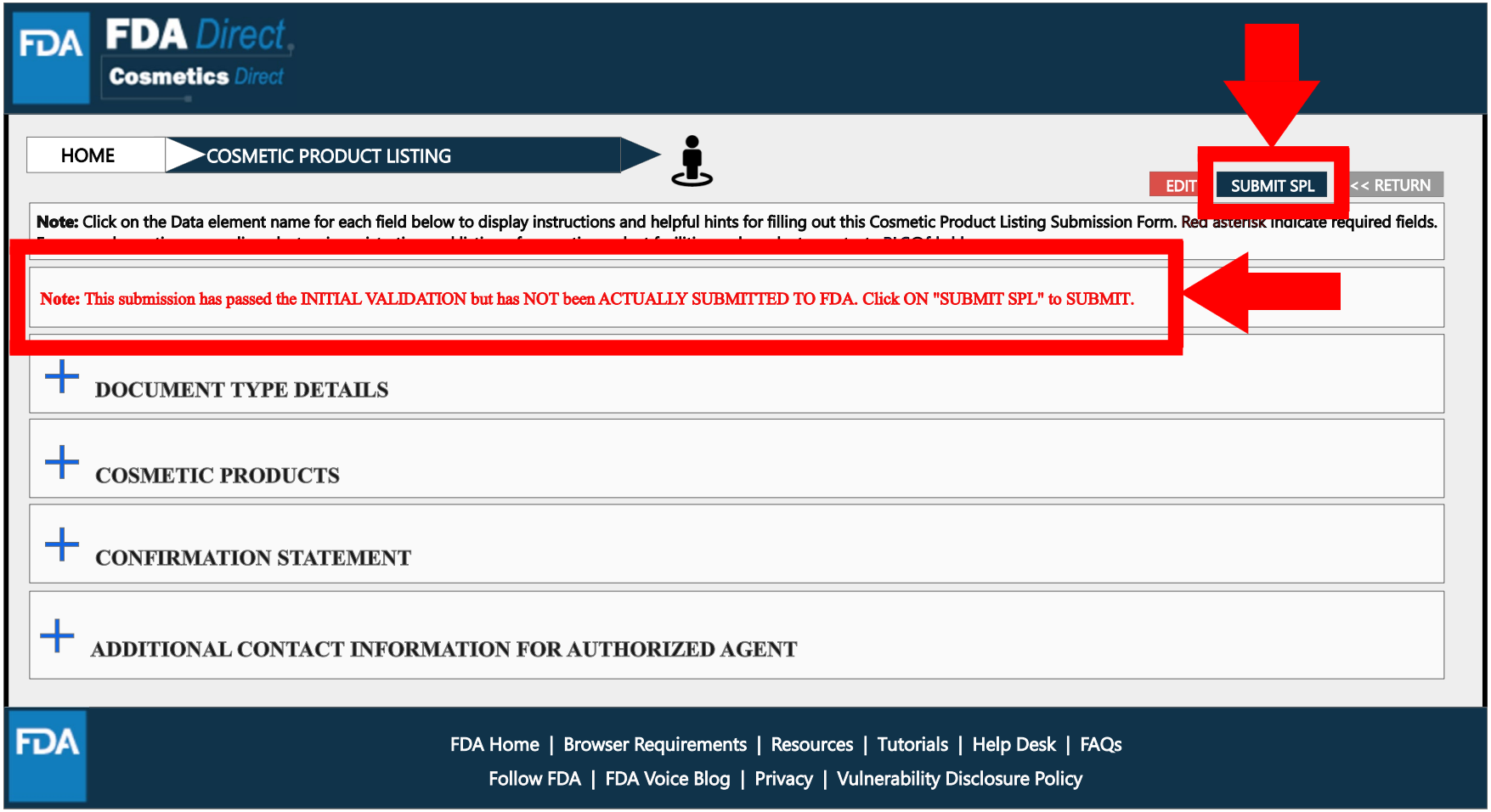
VALIDATE SPL: You can check your SPL for an initial validation before submitting to FDA. This option does not automatically submit your SPL to FDA, even if it passes the initial validation, but scans for certain errors prior to the actual submission. Once the system has completed a quick VALIDATION, the status **VALIDATION IN PROGRESS** will change to **READY FOR SUBMISSION**.



Listing Status: Ready for Submission to Submit SPL

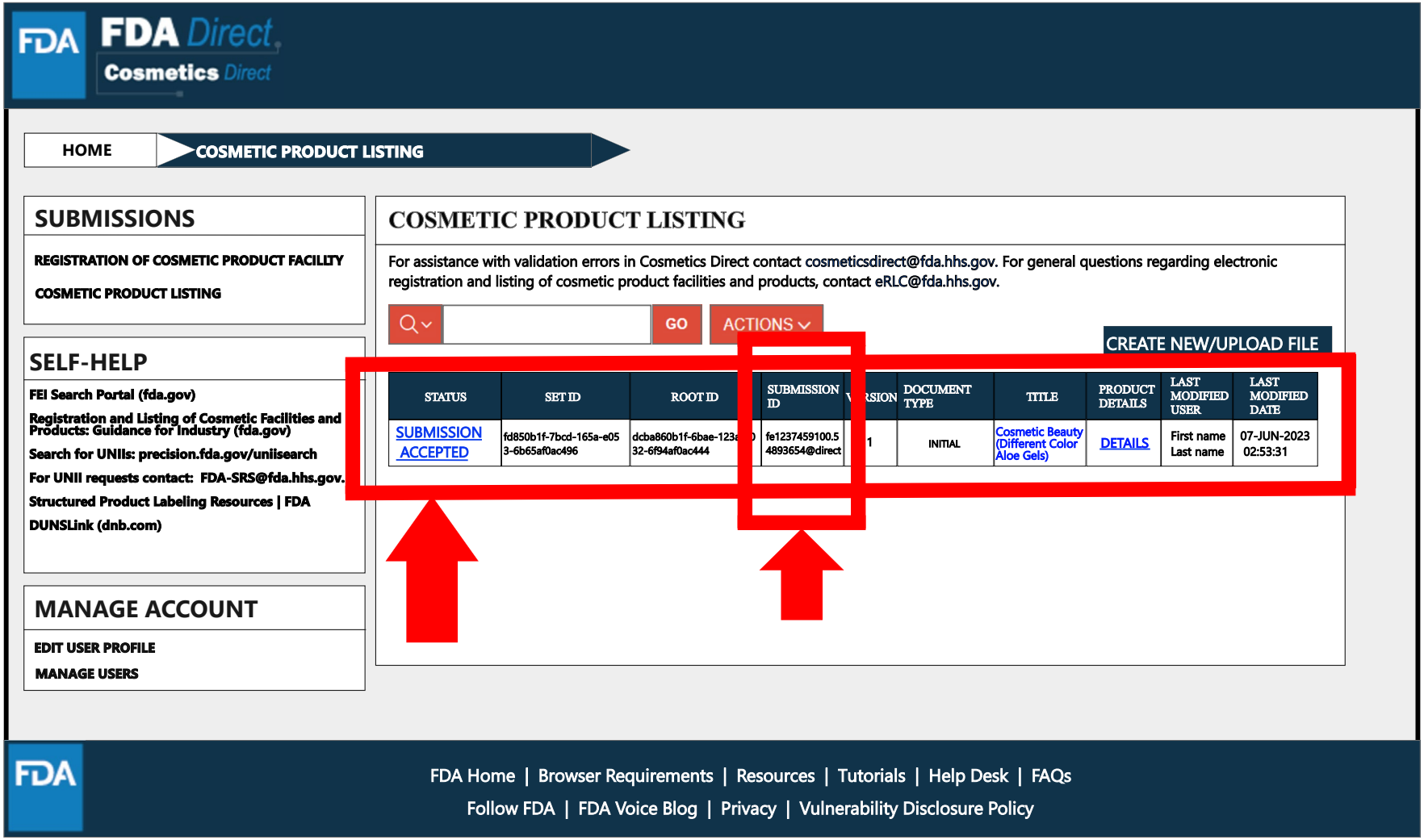
By clicking on the **READY FOR SUBMISSION**, the listing will be ready for **SUBMIT SPL**.

The system will generate a message stating that, *This submission has passed the INITIAL VALIDATION but has NOT been ACTUALLY SUBMITTED TO FDA. Click ON "SUBMIT SPL" to SUBMIT.*



Listing Status:
Submit SPL to Submission Accepted

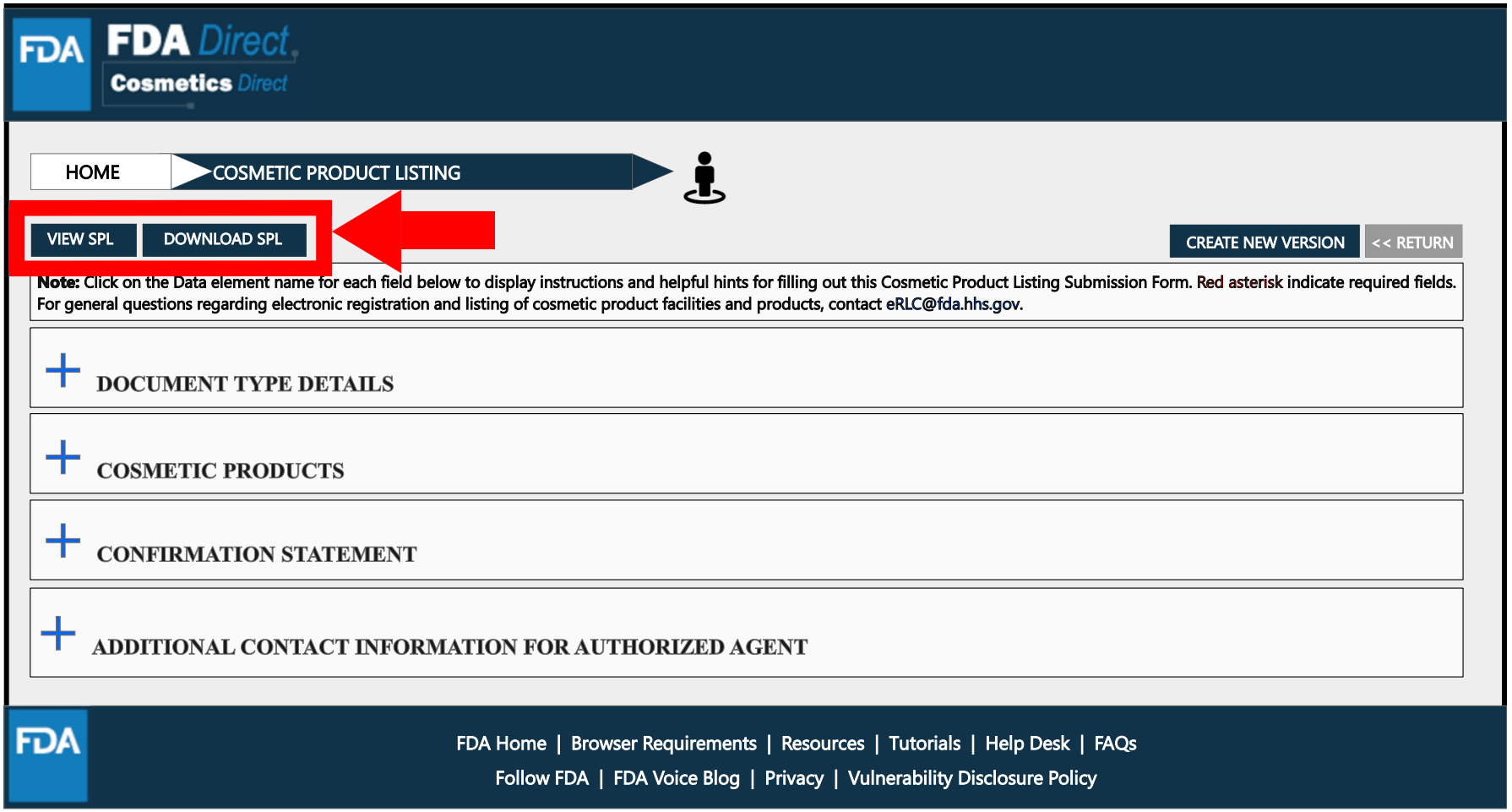
The status will change to **SUBMISSION ACCEPTED** after listing had been successfully completed. A **SUBMISSION ID** will be given to all **ACCEPTED SUBMISSIONS**.



Listing Status:

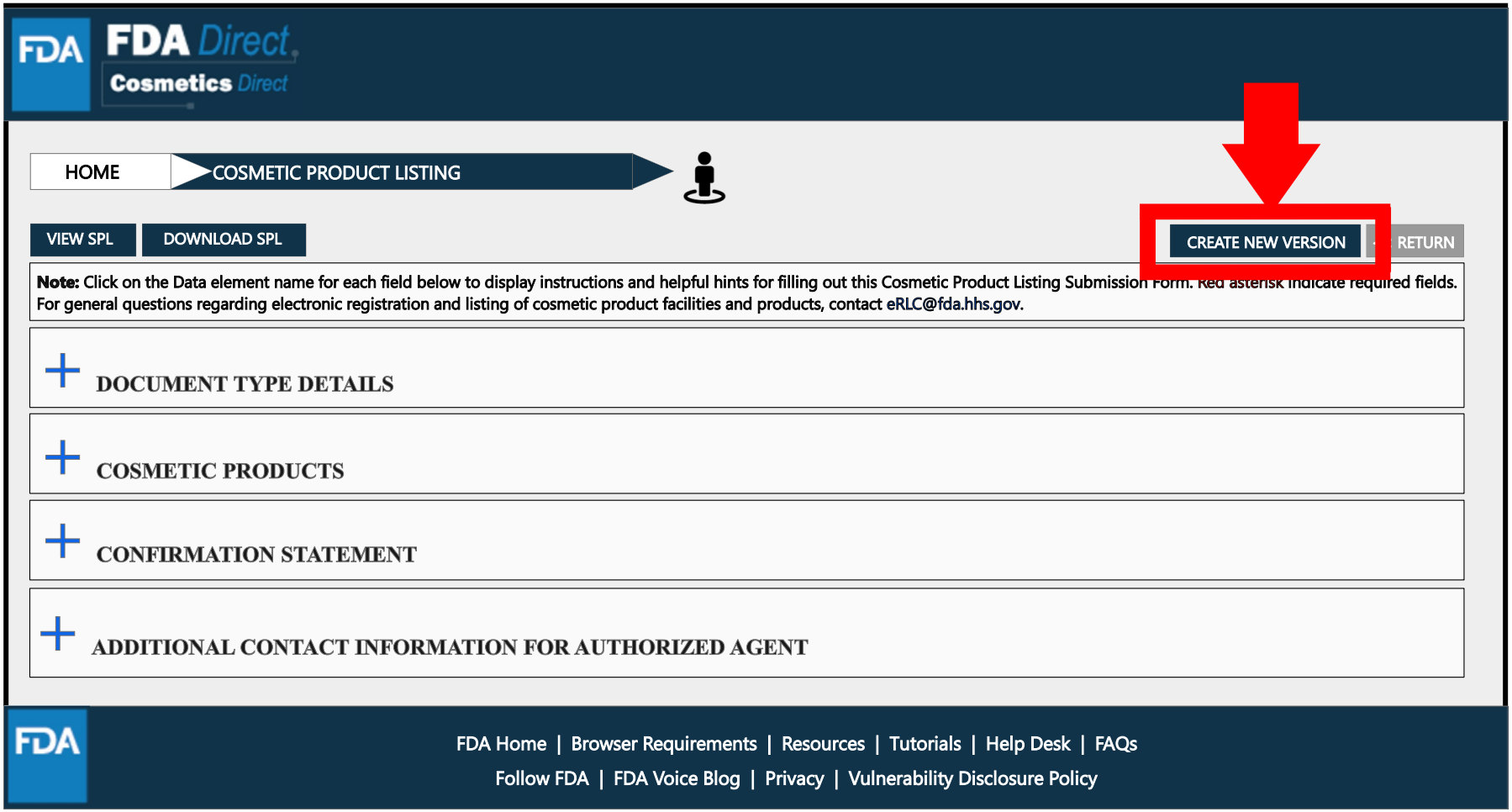
Submission Accepted to View SPL and Download SPL

By clicking on the **SUBMISSION ACCEPTED** the system will allow user to **VIEW SPL** and **DOWNLOAD SPL**.



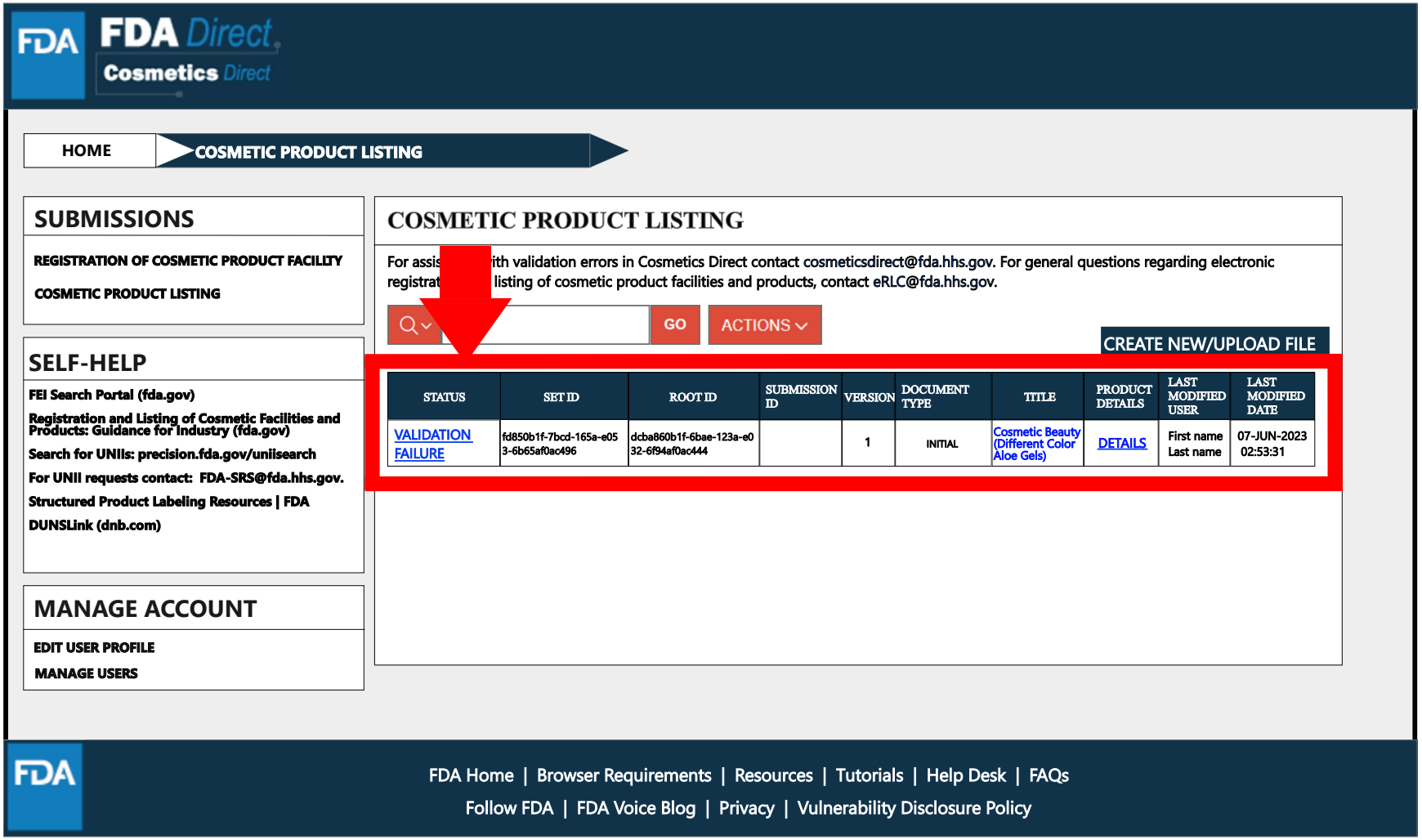
Clone Successfully Submitted SPL

By clicking on the **CREATE A NEW VERSION**, you can clone a successfully-submitted SPL as a starting point.



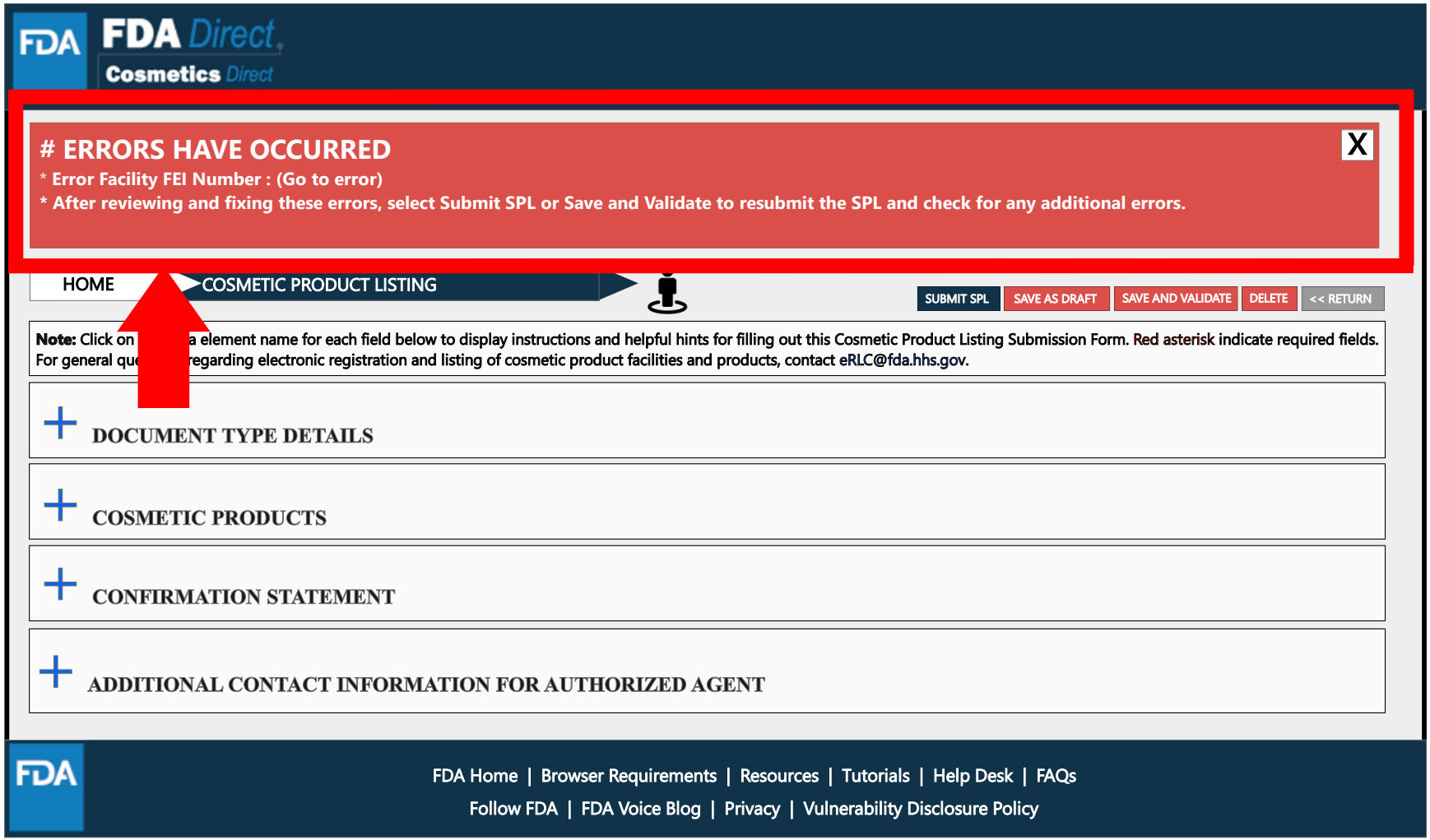
Listing Status: Validation Failure

After SAVE AND VALIDATE, the cosmetic product listing home page will have the following details as shown below. The status will be in **VALIDATION IN PROGRESS**. However, if the system finds any errors the status will change to **VALIDATION FAILURE**.



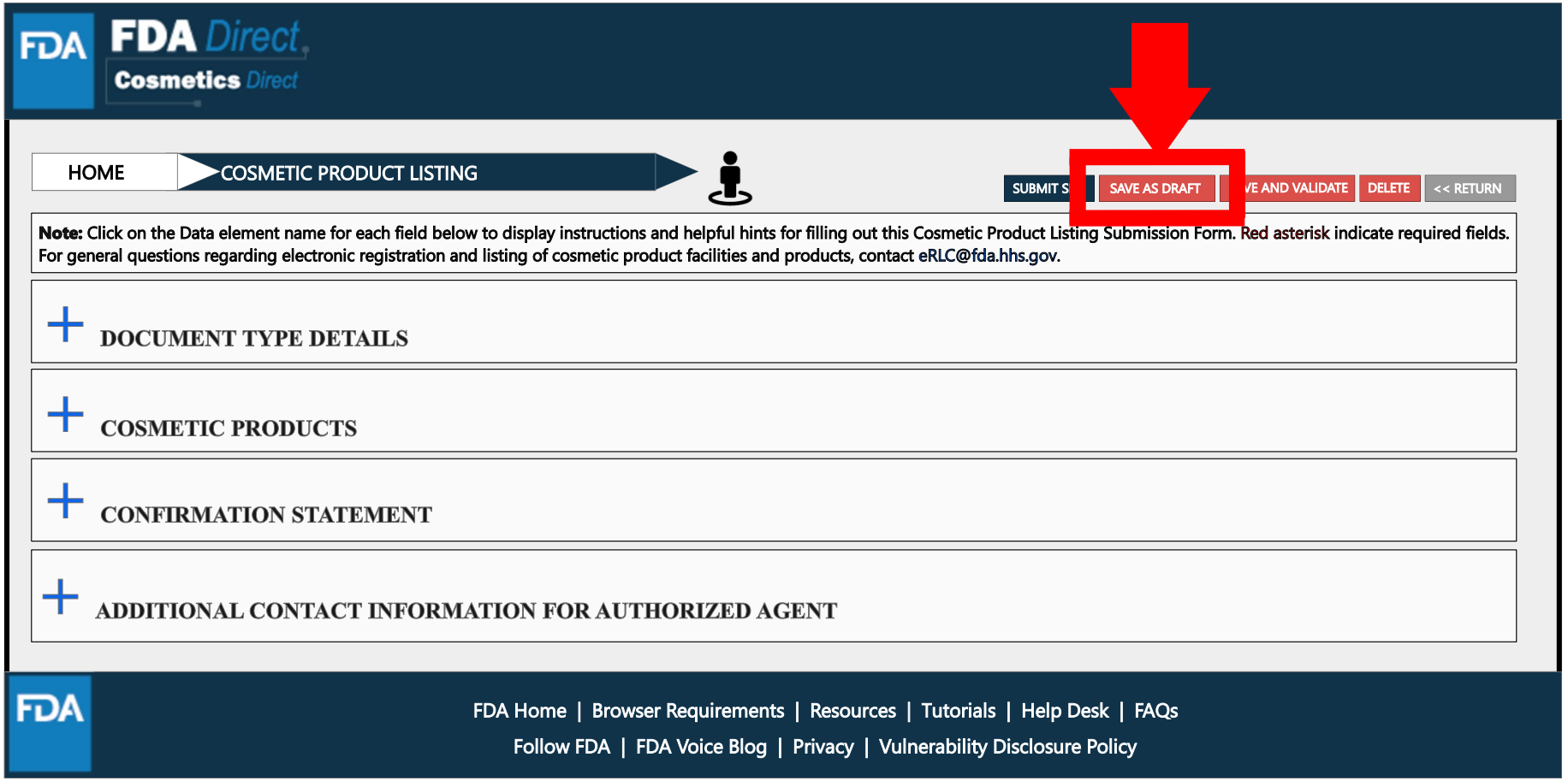
Listing Status: Validation Failure

After selecting the **VALIDATION FAILURE** status, the system will provide a list of errors, that need to be fixed before submitting the SPL. After reviewing and fixing the errors, users can select **SUBMIT SPL** to resubmit the SPL or **SAVE AND VALIDATE** to check for any additional errors.



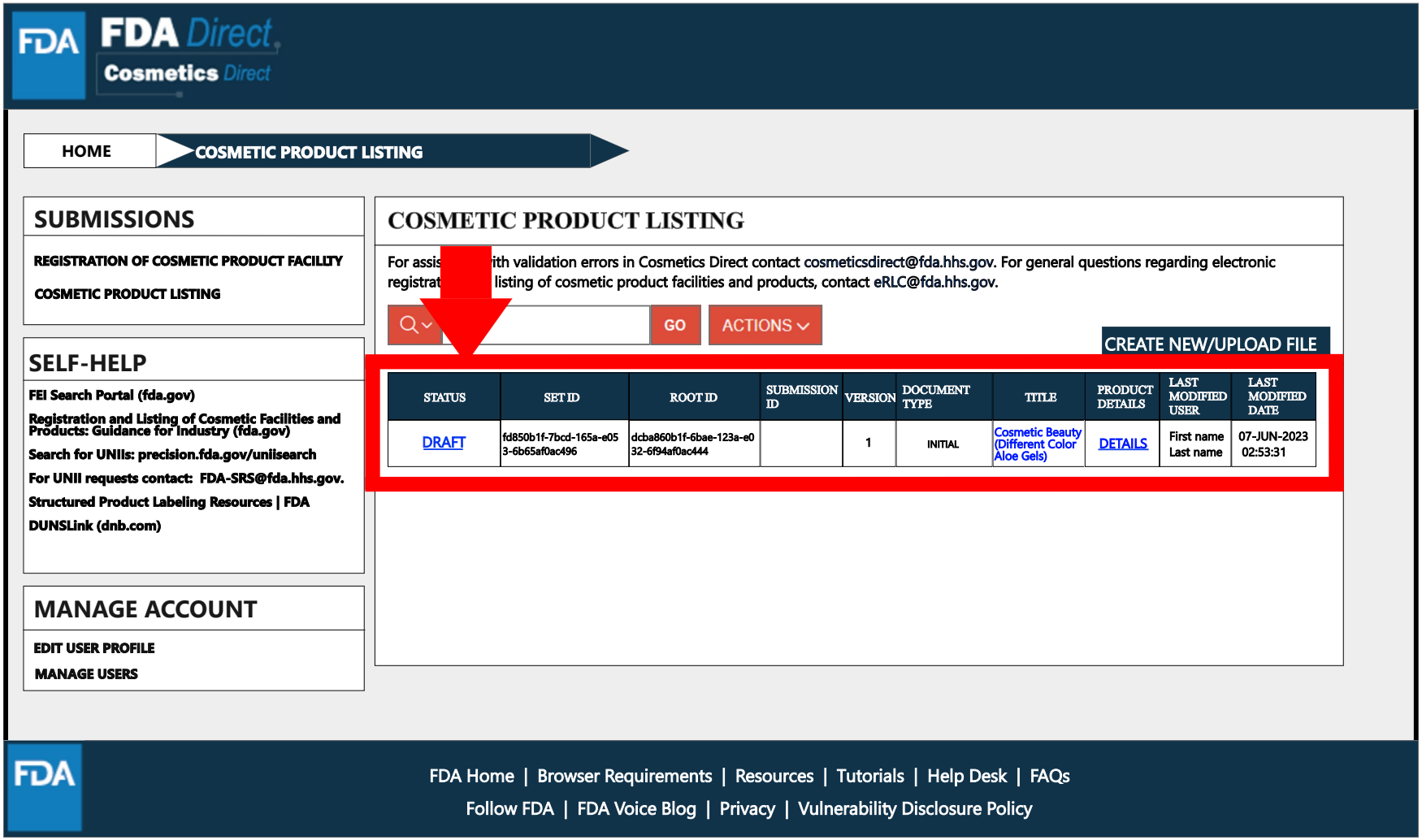
Listing Status: Draft

By selecting **SAVE AS DRAFT**, from any screen during the process of cosmetic product listing, the system will save all information and will bring the user back to the home page. The status will be in **DRAFT**.



Listing Status: Draft

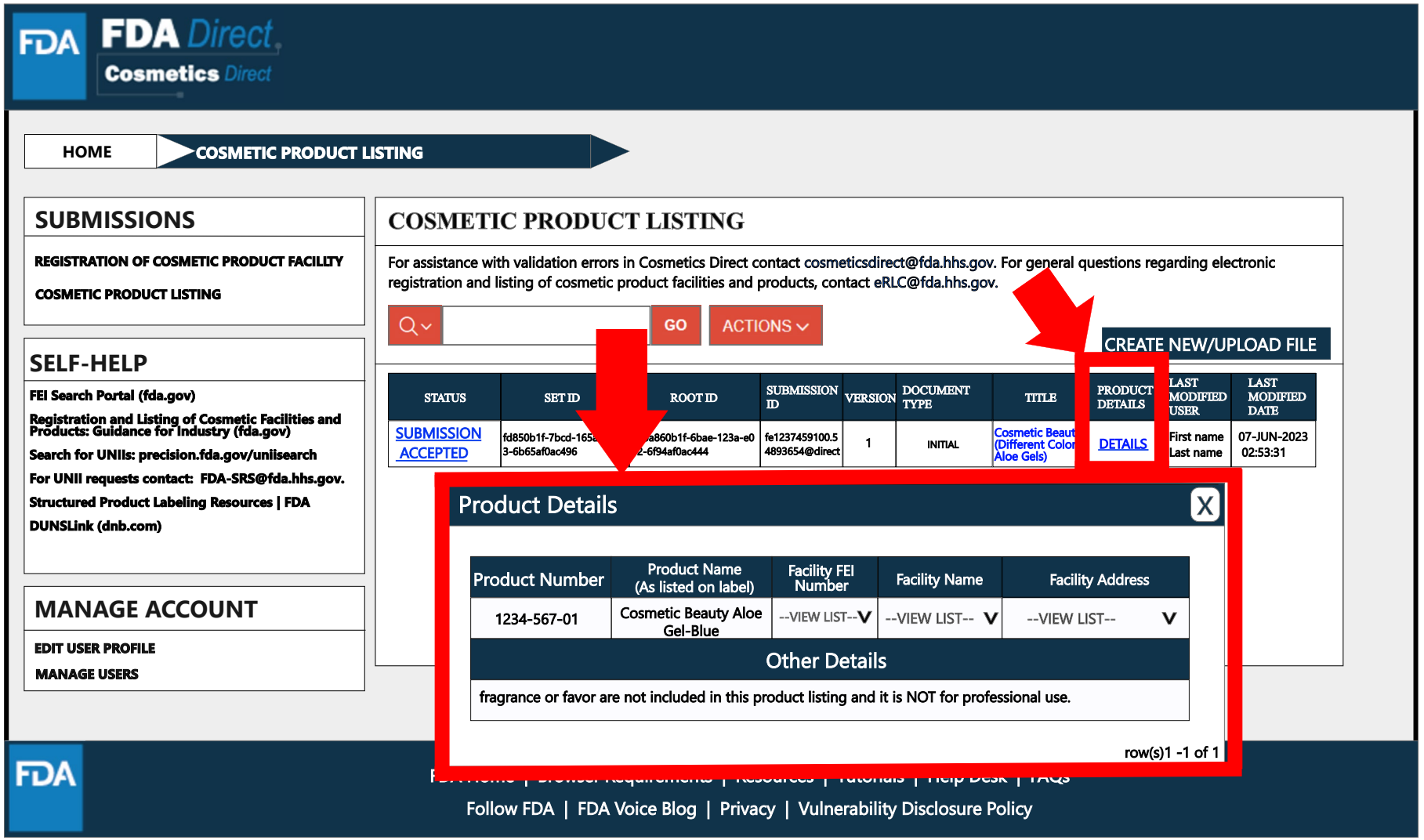
The registration of cosmetic product facility home page will have the following details as shown below. The status will be in **DRAFT**.



Cosmetics Direct Home Page

Details

By clicking on the **DETAILS**, the system will pop-up **PRODUCT LISTING DETAILS** box with information a shown below.



Cosmetics Direct Home Page
All Submissions